YOU *CAN* SAVE MONEY ON PRESCRIPTION DRUGS — PAGE 8

Gore's Vision: A Single-Payer Nation PAGE 2

Health Care News

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Oregon Voters Rebuff Single-Payer Measure

BY CONRAD F. MEIER

Seventy-nine percent of Beaver State voters on November 5 rejected a plan to have government officials run a health care system for the state's 3.5 million residents. Measure 23, touted by supporters as "health care for all Oregon," attracted just 204,082 votes, 21 percent of the total, while 786,768 voters—79 percent—rejected the plan.

"Oregonians' refusal to become single-payer guinea pigs repudiates those advocates who would take away people's right to choose their own health insurance," exulted Donald Young, MD, president of the Health Insurance Association of America (HIAA). "The magnitude of their rebuff should clearly discourage the single-payer special interests from pushing their ill-conceived views of health care in other states and in the Congress."

But the measure's supporters claimed to be undaunted by the defeat. Mark Lindgren, campaign chairman of Health Care for All-Oregon, said they would try again in 2004. "It took decades to free slaves and give women the right to vote," he noted.

Less than a month before the vote, a *Portland Tribune* poll showed supporters and opponents of the measure split almost evenly, with 25 percent of

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Rx Patents SEE CENTERSPREAD

Jennifer Boudreaux R.Ph., co-owner of the Compounding Pharmacy in Shreveport, Louisiana, searches for the generic equivalent of a drug to fill a customer's prescription. During a White House speech on October 21, President George W. Bush proposed regulations that would make generic drugs available to the public more quickly. *(Photo by Mario Villafuerte/Getty Images)*

Bush Acts to Limit Rx Patent Protections

BY CONRAD F. MEIER

President George W. Bush announced on October 21 his plan to speed up the process of getting generic drugs to the marketplace. He called the move "another important advancement in the cause of bringing more affordable prescription medicines to our seniors."

Under the new Bush rules, which do not require congressional approval but are subject to a public comment period, pharmaceutical companies would be permitted just one 30-month patent extension per patented drug. Currently, brand-name pharmaceutical manufacturers can stave off competition from generics by getting the Food and Drug Administration's approval for multiple patent extensions on a single medication.

Brand-name drug manufacturers sometimes file lawsuits against generic drug makers getting ready to market a less-expensive version of a brand-name product. The lawsuits invoke the 1984 Hatch-Waxman Act, which was meant to promote competition in the drug industry but gives brand-name makers up to 30 months of patent protection if they go to court to challenge a generic version of their drug on patent infringement issues. By claiming to have a patent on their packaging and various modifications to their brand-name drug, they sometimes win multiple 30-month extensions.

The new rules make it clear that drug companies cannot file patents on such product aspects as packaging changes, metabolites, and intermediates that are unlikely to represent significant innovations to the original drug. Drug makers would also be required to

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Free-market Reformers Are Winners in Election 2002

BY JOE MOSER

The 2002 election was not a referendum on health care issues. A post-election survey by pollster Dr. Whit Ayres found only 9 percent said health care was the issue that had the most influence on their vote. Health care trailed the economy (29 percent), terrorism (20 percent), and education (16 percent).

An analysis of key races, however, finds candidates who talked about sensible free-market solutions to health care issues fared better than those who advocated big-government solutions.

One telling event was voters' decisive rejection of the Oregon single-payer health care initiative,

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Al Gore Wants a Single-Payer Nation

BY CONRAD F. MEIER

Former Vice President Al Gore is back from hibernation seeking the Democratic Party nomination for the Presidency in 2004.

In a November announcement, Gore says he favors single-payer health care. He promised to unveil a health care overhaul that would rival Bill and Hillary Clinton's infamous attempt to socialize medicine in the United States. Like the failed Clinton plan, the Gore proposal likely will require complicated regulations and a huge bureaucracy to dictate how Americans access health care.

Greg Scandlen, senior fellow at the National Center for Policy Analysis and an assistant editor for *Health Care News*, was quick to respond to Gore's news. "I'm afraid Mr. Gore's support for single-payer means he is afraid he won't get the Democratic nomination otherwise. He is throwing a bone to the Far Left of the party to secure the nomination, and he is hoping once he is nominated a miracle will get him elected."

At a synagogue in New York during his November book tour promoting *Joined at the Heart*, Gore warned, "I think we've reached a point where the entire health care system is in impending crisis. I have reluctantly come to the conclusion that we should begin drafting a single-payer national health insurance plan."

The former Vice President believes the money that pays for health care—including insurance premiums and tax dollars—should be collected by a single government agency, which would then pay for comprehensive health care coverage for all Americans, in a fashion similar to the health care systems of England or Canada.

Scandlen told *Health Care News*, "It's a Hail Mary pass. Al Gore surely knows the countries that already have single-payer are in no better shape than we are—worse in fact. The people in Canada and the UK are no happier with their health care systems than Americans are with ours. Doctors and nurses are fleeing those systems, they don't have decent equipment or facilities, and people are dying while waiting to get services."

Gore's comments were first reported by ABC News' Internet political report "The Note" and were confirmed by Gore spokesman Jano Cabrera, who said details would come in a future speech on health care.

CNN News reported that calling for a single-payer plan would be a dramatic change for Gore. During the 2000 primary campaign, Gore attacked Democratic rival Bill Bradley's single-payer health care plan, calling it too expensive and not expansive enough to help poor people afford full coverage.

NAS Urges Pilot Projects

In a report delivered to the Bush administration on November 19, the Institute of Medicine, associated with the National Academy of Sciences, agreed with Gore's conclusion that the U.S. health care system is in crisis. It refrained from recommending Gore's federal-level overhaul, however, calling instead for state-level tests of possible solutions.

For more information…

WWW The full text of the November NAS report, "Fostering Rapid Advances in Health Care: Learning from System Demonstrations," is available on the Internet at **http://www.nap.edu/books/0309087074/html/.**

Pointing to insurance premium increases, a growing number of uninsured Americans, and tens of thousands of deaths it said are caused every year by medical errors, the NAS report outlines five areas in which demonstration projects could be used to test strategies aimed at solving the nation's most pressing health care problems. A 16-member NAS panel suggested three to five states experiment with universal insurance coverage, either through tax credits or by expanding such government programs as Medicaid or the State Children's Health Insurance Program; medical malpractice reform, perhaps by encouraging patients to waive jury trials in exchange for quicker compensation; plus community health centers, better treatment for chronic illnesses, and improved computer technology.

Not Gore '04

Top Republican Dick Armey (R-Texas) saw the Gore promise of a health care overhaul as a purely political move, one he welcomed. Armey told the media, "I would love a rematch with Al Gore. I would see nominating Al Gore as tossing in the towel."

Only about one-third of Democratic Party insiders think Gore should run for President again. According to a *Los Angeles Times* poll, 312 Democratic National Committee members—roughly three-quarters of the committee's total membership—say none of the top possible candidates stands out as having particularly broad support.

In a separate poll released by Time and CNN, just over a third of Americans think there is a Democrat who can defeat President Bush in 2004. Half think there is not. Among Democrats and those leaning Democratic in the general population, only 36 percent in the Time-CNN poll favored Gore, while 26 percent said they would support Sen. Hillary Rodham Clinton, also a well-known advocate of single-payer health care.

Getting Attention

Merrill Matthews Jr., director of the Council for Affordable Health Care (CAHI) and a senior fellow with The Heartland Institute, doubted whether Gore's new plan would succeed where others failed.

"Since Gore didn't win the Presidency, he has been trying to get the public's attention—and this certainly got mine," Matthews said. "He tried a government-run health care system before, calling it universal health care. When Gore and the Clintons tried to impose universal health care upon the American people they practically destroyed it!"

Matthews continued, "With all the discussion about Democrats needing new ideas, this certainly is not one of them. This tired idea goes back to the days of Harry Truman! For many Democrats, the only solutions to rising health insurance premiums and the growing number of uninsured are more price controls, more government interference, and more bus trips to Canada."

Linda Gorman, senior fellow at the Independence Institute, agreed, telling *Health Care News*, "Single-payer systems have been tried in a number of countries. In every case, government control of care has resulted in higher costs, lousy patient care, and slow technological innovation.

"Government systems in the United States, notably the Veterans Administration, military health care, Medicare, and Medicaid have the same problems," she continued. "These problems are inherent to the way all government systems operate. Mr. Gore does not have a magic wand."

Recommends CAHI's Matthews, "If Al Gore truly wants to improve the American health care system he should look at insurers like Aetna, Fortis, Destiny, and Vivius, which have created new and innovative ways to get affordable health insurance to those who need it.

"These insurance companies," said Matthews, "and the American people need a free and open marketplace to take advantage of affordable health insurance. More government regulations will only make things worse."

Conrad F. Meier is managing editor of Health Care News.

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The PULSE

BY GREG SCANDLEN

FREE-MARKET HEALTH CARE REFORM IN THE NEWS

Now it's President Bush's Turn

President George W. Bush (top) has received a great deal of input on a new health care agenda in the U.S. from Mark McClellan (above left), Bobby Jindahl (above), and other key advisors.

Let's take a look at the elections and how they will influence health care issues in the new Congress.

First, this is without a doubt George W's election. He finally gets the mandate that eluded him two years ago. His campaigning and his coattails made all the difference. This means the President is the undisputed champion of the Republican Party, and Congressional Republicans owe him big time.

He will set the agenda and they will rally around the President's flag. The President is very likely to make health care a high priority in the new Congress. He understands the need (as does Karl Rove) to seize the initiative on domestic policy and build a track record of accomplishment in time for the 2004 elections.

And thanks to the work of Mark McClellan, Bobby Jindahl, and other bright lights, the administration has a comprehensive, far-reaching agenda for health reform all ready to go. It includes tax credits for the uninsured, association health plans, expansion of MSAs and FSAs, malpractice reform, growth of safety net public health clinics, and targeted prescription drug assistance for low-income seniors. That is not the be-all-and-end-all for health reform, but it represents a giant step in the right direction.

Once all that is under our belts, we can go on to fundamental reform of Medicare and Medicaid. Hold on to your hats. The next six months should be a wild ride.

Senator Baucus Sends Letter to Secretary Chao

The myth that the tax credits for uninsured workers created by the Trade Act disallow individual insurance has become a liberal mantra, echoed in a letter by Sen. Max Baucus (D-Montana) to Labor Secretary Elaine Chao.

Baucus is wrong on several counts, beginning with the spelling of the Secretary's name—the letter misspells it "Chow," as in "Puppy Chow," three times. (Of course, if a Republican had made that mistake he would be accused of disrespect and cultural insensitivity, the *Washington Post* would be demanding an apology, and Tom Daschle would demand the offender's resignation.) But Baucus doesn't get the substance right, either.

The point of his letter is to intimidate the Department of Labor from allowing state flexibility in providing coverage. He says, "(The conference committee) did not intend to allow states to enter into arrangements with individual insurers through the state-based coverage options. ... Any other interpretation of the law would be a violation of the intent of its authors." He also thinks the requirement for three months of continuous coverage should apply only to the time prior to becoming unemployed. After that, they can go as long as they want without coverage on a guaranteed-issue basis.

Rep. Thomas Corrects Baucus Misrepresentations

Baucus sent copies of his letter only to Secretaries O'Neill and Thompson, but House Ways and Means chairman Bill Thomas (R-California) acquired a copy and forwarded his own thoughts to Secretary Chao. Thomas writes in his capacity as chairman of the conference committee to correct Baucus' suggestion "that his letter spoke for the Trade Act conferees..."

Thomas says, "Specifically, Senator Baucus contends that the conferees did not intend to allow states to enter into arrangements with individual insurers through state-based coverage options. That is exactly what the conferees intended." Thomas quotes the section of the law that allows a state to enter into an arrangement with "a group health plan, an issuer of health insurance, an administrator, or an employer." He adds, "The language is quite clear: states may contract with insurers in the individual market to provide health coverage for eligible individuals."

Thomas also objects to Baucus' interpretation of the three-month continuous coverage provision. He notes that allowing people to go without coverage for an unlimited amount of time would create "a significant adverse selection problem ... as people would wait until they got sick before buying health insurance." He concludes, "When the conferees agreed to these provisions, we were very clear as to what each meant and their practical impact on disaffected workers."

Thomas, by the way, spells Secretary Chao's name correctly and has the courtesy to send Baucus a copy of the letter.

Source: These are pretty short letters, but for some reason, very large pdf files. I will send you copies if you email me at GMScan@aol.com *Please include "Baucus" in the subject head.*

Washington Post Distorts Definity Numbers

The *Washington Post* ran a major article about consumer-driven plans in its Health section. The article by Melody Simmons is a fairly good description of the concept, though she gets her numbers wrong in trying to illustrate how they work.

Like most things in Washington, the article was prompted by a new federal initiative. Specifically, the Postal Workers Union will be offering a Definity plan to federal employees this year in its FEHBP program. This is important because all 9 million federal employees are eligible to sign up for the program by paying a small membership fee.

It is also interesting because the federal unions have fought tooth and nail against various efforts to get MSAs included in FEHBP. Simmons says the premium for the program is "slightly higher than most federal employee HMOs but as much as 20 percent less than a typical PPO plan." Each individual will get $1,000 to apply towards a $1,600 deductible (double those numbers for families). After reaching the deductible there is an 85/15 coinsurance for services within the PPO up to a $4,500 stop-loss limit and 60/40 for out-of-network services (up to $9,000).

Simmons quotes Families USA's Ron Pollack as calling these plans "a wolf in sheep's clothing," designed merely to shift costs from employers to workers. She then works through some "hypothetical" family situations and concludes the consumer-driven product would be more expensive than the other options.

But her numbers don't add up, and she plumb forgets to subtract the $2,000 cash account from the family's out-of-pocket costs. I expect the numbers came from Ron Pollack, and Simmons took them at face value—never a good idea when dealing with Families USA. Still, she concludes the plans are designed to "Allow consumers the freedom and flexibility to choose how and when to spend for their care."

Source: Definity sent a blistering reply to the Post, *pointing out Simmons' errors, and the* Post *apologized for them. They apparently have also removed the article from their archives. But Definity's response may be found at:* http://www.washingtonpost.com/wp-dyn/articles/A59337-2002Nov2.html

New Insurance Model Proposed

Finally, writing in *Modern Healthcare*, James Rice argues there is a need for "new insurance products for (our) aging society." He says the "old insurance models are not designed for the exploding costs and complex risks" of a demanding and aging population. He argues, instead, that we need a new insurance product (a "blended senior annuity") that will combine a life annuity, LTC coverage, disability, life insurance, and "managed care health insurance that emphasizes health promotion and disease management." He doesn't much care if this product is offered as a government program or a private product, and he thinks all industrialized societies need to move in this direction.

It is a provocative thought and certainly conforms to growing thinking that health insurance needs to move towards a financial services model, rather than a "prepaid health care" model.

Source: http://www.modernhealthcare.com/article.cms?articleId=27639

Greg Scandlen is senior fellow in health policy at the National Center for Policy Analysis in Dallas, Texas and assistant editor of Health Care News. *To sign up for his free weekly e-newsletter, Scandlen's Health Policy Comments, log on to* http://www.ncpa.org/sub. *Email Scandlen at* GMScan@aol.com.

You are invited to participate in an online discussion list dealing with many of the issues we report on here. To check it out, send an e-mail to ***HealthBenefitsReform-subscribe@yahoogroups.com****. Later on, if you want to drop off, just send an e-mail to* ***HealthBenefitsReform-unsubscribe@yahoogroups.com****.*

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SPN Hosts Health Care Reform Summit

Martin D. Hynes Ph.D. addresses attendees at the State Policy Network Health Care Reform Summit. (inset) SPN President Tracie Sharp welcomed representatives from nearly 50 think tanks across the country to the event.

BY CONRAD F. MEIER

Nearly 50 representatives of public policy think tanks from across the country converged on Indianapolis, Indiana on October 17-19 for the tenth annual meeting of State Policy Network. Attendees were welcomed to the event by SPN President Tracie Sharp.

State Policy Network is the national trade association for state-based free-market public policy research organizations. The group's annual meeting offers networking opportunities, issue updates, and "how to" training for member groups' top executives. The Indianapolis event, under the direction of SPN Chairman Carl Helstrom, mixed leadership development with policy mobilization workshops featuring nationally known keynote speakers.

No Ordinary Day

The meeting opened on October 17 with a summit focused on health care issues. Attendees were shuttled from The Omni Hotel to the Eli Lilly Corporate Center for a day of information-sharing that included a tour of the Lilly facilities.

"We are here to learn and to share with each other what we know about market-driven health care," explained Grace-Marie Turner, president of the Galen Institute. "We are here," she said, "to exchange information on what is working and what is not working at the state level."

Turner introduced Dr. Martin Hynes, head of pharmaceutical product development at Lilly. Hynes addressed the product development cycle and timeframe, the costs involved in research and development, and the low probability of success in developing a drug that actually makes it to a consumer's medicine cabinet.

Hynes addressed the widely held myth that the federal government, rather than private-sector drug manufacturers, fund the bulk of pharmaceutical development. "This misunderstanding," said Hynes, "incorrectly leads the consumer to think prescription drugs should cost less."

Economic Dynamic

The Hynes presentation was followed by an interactive panel discussion on "The Economic Value of Innovation." Panelists included Wade A. Lange, president and CEO of Indiana's Health Care Industry; Dr. Gail H. Cassell, vice president of scientific affairs for Lilly; Nina Owcharenko, health policy analyst at The Heritage Foundation; and Merrill Matthews PhD, director of the Council for Affordable Health Insurance (CAHI) and senior fellow at The Heartland Institute.

Panelists discussed how market forces work to the advantage of companies and their communities and, conversely, how price controls and other anti-market interventions undermine value and threaten future investments directed at innovations in pharmacology. Cassell reminded the audience, "Progress can happen only with the cooperation of the private sector, academia, and the government."

Panel members also examined how reduced profits result in economic loss to the community and change the dynamics of corporate decisions on future research and development.

A second panel asked, "Are States Rationing Innovation?" Linda Gorman, senior fellow at the Independence Institute; Dr. Robert Browne, a medical advisor at Lilly; Steve McCaffery, president and CEO of the Indiana Mental Health Association; and James Frogue, director of the American Legislative Exchange Council's health and human services task force, led a discussion that included substantial give-and-take with the audience.

"Two roundtable discussions in the afternoon addressed the nuts-and-bolts of communicating reform ideas."

Gorman passed along a true story about a state health care official in Oregon, who told a consumer of the state-run Medicaid health care plan, "Just because you are covered by the Oregon health care plan does not mean you have a right to health care."

Communicating Health Care Reform

Two roundtable discussions in the afternoon addressed the nuts-and-bolts of communicating reform ideas. "The Policy Successes and Failures" session was handled by Paul Guppy of the Washington Policy Center; Kurt Weber, Cascade Policy Institute; Dr. David MacDonald, American Association of Patients and Providers and co-founder of SimpleCare; John McClaughry, president of the Ethan Allen Institute; and Harry Messenheimer, president of the Rio Grande Foundation.

The "Marketing and Media Strategies" session presented opportunities to learn how to better communicate and implement new ideas in an emotional and complicated policy arena.

A lively discussion of how to battle single-payer health care proposals raised questions about labeling. Some in the audience considered it "too dramatic" to label single-payer proposals "socialized medicine," saying the phrase "turns people off."

Others recommended "it's time to play the same game as our liberal activist opponents play," calling "a spade a spade" and never forgetting that the proponents of single-payer don't hesitate to "call us rats and roaches living off the free-market."

When given the opportunity to share Heartland's perspective on what makes for successful communication, I held up a copy of *Health Care News* and spoke about the value of this one-of-kind hard-copy newspaper and Internet publication.

"*Health Care News* reaches 8,000 elected officials, around 500 media types, has a growing circulation pushing 30,000 copies, and fills the information gap with health care news mostly ignored by the mainstream media," I said in one long breathless statement. "If," I followed up before sitting down, "you want your messages, your ideas communicated and implemented, support *Health Care News* and send me your written material."

Not Over 'Til It's Over

The health summit concluded with a dinner hosted by Lee Tooman, vice president of government relations for Golden Rule Insurance Company. The event's closing speaker, introduced by Tooman, was John Hartnedy, director of the Arkansas Department of Insurance, who offered a unique perspective on Medical Savings Accounts and their potential for revolutionizing the insurance industry.

Conrad F. Meier is managing editor of Health Care News.

The event took place at Eli Lilly Corporate Center for a day of information-sharing that included a tour of the facilities.

For more information…

WWW Audiotapes and Power Point slide presentations from the SPN's Health Care Reform Summit are available from SPN President Tracie Sharp. Contact her at **sharp@spn.org** ... and tell her you saw it in *Health Care News*!

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ELECTION continued from page 1

Measure 23. Oregonians overwhelmingly rejected this universal health care scheme 79 percent to 21 percent.

Under the proposal, all public and private health care payments, including Medicaid and Medicare, would have been funneled into a "single-payer" account controlled by the government. Because payment decisions would have been made by government bureaucrats, the system would have led to rationing of care for patients and an exodus of physicians from the state.

A study conducted by LECG Consulting showed every Oregon taxpayer would have paid an additional $4,000 to $5,900 in taxes to pay for the single-payer system. That would have been devastating to Oregon's economy.

Prescription Drugs

The Medicare prescription drug benefit passed by the House of Representatives in June 2002 gave Republican candidates an edge on an issue that traditionally favors Democrats.

The House bill used competing private health plans to administer a drug benefit for senior citizens at a cost of $350 billion over the next 10 years.

Several House incumbents who had been targeted for defeat, including Rep. Nancy Johnson (R-Connecticut) and Rep. John Shimkus (R-Illinois), could point to their support of the House bill as proof they did something to help seniors with high prescription drug costs. Both won their races.

The House bill also laid the groundwork for Senate candidates to take the lead on the issue. Representatives John Sununu (R-New Hampshire) and Saxby Chambliss (R-Georgia) could tout their support of the House bill in their Senate races. Both won, with Chambliss pulling off one of the biggest upsets of the election cycle, defeating Democratic incumbent Senator Max Cleland.

Victories by Jim Talent (R-Missouri), John Cornyn (R-Texas), Norm Coleman (R-Minnesota), and Elizabeth Dole (R-North Carolina), all of whom supported the market-based reform approach taken by the House bill, were crucial to the change in control of the Senate.

"An analysis of key races ... finds candidates who talked about sensible free-market solutions to health care issues fared better than those who advocated big-government solutions."

The Democrats' message didn't seem to resonate with voters. Many, including Sen. Jean Carnahan (D-Missouri), Gov. Jeanne Shaheen (D-New Hampshire), and former Vice President Walter Mondale (D-Minnesota) supported a big government-run prescription drug benefit within the current Medicare program that could cost up to $1 trillion over the next 10 years.

The issue of prescription drug prices also played a role in many races. Democrats were generally in favor of taking measures to promote the use of generic drugs and to reimport prescription drugs from other countries.

Republicans, particularly Sununu and Rep. John Thune (R-South Dakota), were aided by President George W. Bush's announcement in early October to limit pharmaceutical companies to one 30-month stay on a drug patent when challenged by generic drug manufacturers. That afforded Republican candidates the opportunity to say they were doing something about the high cost of prescription drugs. Sununu won, but Thune was narrowly defeated by incumbent Senator Tim Johnson (D).

On November 14, members of the freshman class of the 108th Congress posed for a group photo on the steps of the U.S. Capitol. When they take office in January, they will face head-on such health care reform priorities as tax credits for the uninsured and tort reform for medical malpractice. *Photo/Mark Wilson*

Health Care Costs

Rising health care costs and access to care were important issues in many campaigns. Conservative candidates were successful in articulating a positive message that included the expansion of Medical Savings Accounts (MSAs) and creation of Association Health Plans. Liberals advocated expansion of coverage for the uninsured primarily through existing government-run programs, including Medicaid and the State Children's Health Insurance Program.

House candidates Chip Pickering (R-Mississippi), Clay Shaw (R-Florida), and Chris Chocola (R-Indiana) were among those successful in touting MSA expansion as a solution to rising health costs. They advocated making MSAs permanent, tax-exempt, and available to all small business employees and individuals who purchase their own insurance.

Victorious Senate candidates Lamar Alexander (R-Tennessee) and Talent were also helped by their support of health insurance purchasing groups for small businesses. Called Association Health Plans, these allow small businesses to enter into purchasing pools to provide health benefits while avoiding costly mandates and gaining the same discounts for which large firms qualify.

Medical Savings Accounts and Association Health Plans are consumer-driven approaches voters seemed to like. They were a positive message in an environment where consumers seem to be seeking more choice and control over their health care decisions.

The New Landscape

While the 2002 elections may not have produced a mandate for free-market health care reform, advocates of market-driven approaches now see an environment undoubtedly more receptive to their ideas than before.

"[I]n the 108th Congress, ... priorities on health care reform include a targeted Medicare prescription drug benefit, tax credits for the uninsured, and tort reform for medical malpractice."

With Republicans in control of the White House, House, and Senate, we can expect a revisit of free-market principles in health reform in the coming year. President Bush, House Speaker J. Dennis Hastert, and Senate Majority Leader Trent Lott all have said health care legislation will be a top priority in the 108th Congress.

Specifically, their priorities on health care reform include a targeted Medicare prescription drug benefit, tax credits for the uninsured, and tort reform for medical malpractice.

A prescription drug benefit for Medicare beneficiaries that includes broader reforms in the Medicare program and uses the private sector to administer the benefit now stands a better chance of advancing in the Republican-controlled Senate. It is imperative Republicans act on a prescription drug benefit in the upcoming Congress, lest voters hold them responsible for inaction in the 2004 Presidential election year.

How to assist the 41.2 million Americans without health insurance is an issue policymakers will probably have to address in the coming session. Giving the uninsured tax credits to purchase private health insurance is a free-market approach to this problem with bipartisan support in Congress. The Trade Act of 2002 contained tax credits for uninsured workers who lost their jobs due to trade negotiations and seed money for establishing and funding High-Risk Insurance Pools.

Limiting medical malpractice awards is a must issue to address at both the state and federal levels. The 2002 House bill capping noneconomic damages at $250,000 stands a better chance of passage by the Republican-controlled Senate and has the backing of the President.

Medical malpractice reform also stands a better chance in the states, where Republicans netted four state legislative chambers and now have control of both chambers in 21 states, compared to 16 for Democrats. Republicans also retained control of governorships by a 26 to 24 margin.

Overall, the 2002 election brightened the prospects for free-market health reform in the coming years. The voters have spoken, choosing men and women who endorse market-based, consumer-driven health care solutions over big government.

Joe Moser is a health policy analyst at the Galen Institute, a not-for-profit public policy research organization based in Alexandria, Virginia. The views expressed here do not necessarily reflect the views of the Galen Institute.

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Health Affairs Analysts Stir Up Controversy

Mark Pauly, Len Nichols expose debate over nongroup insurance market as "short on facts, long on opinion"

BY GREG SCANDLEN

An October *Health Affairs* report by Mark Pauly and Len Nichols, calling itself "a roadmap through the areas of agreement and disagreement in a critical debate on how to solve the problem of too many uninsured Americans," attracted a flurry of reaction papers and spawned a day-long conference on the topic by the Center for Studying Health System Change.

Economists Pauly and Nichols contend tax credits for the purchase of individual health insurance could stimulate the growth of that shrinking insurance market, helping to reduce the number of uninsured Americans. Sorting through the economics of tax credit proposals is fairly easy ... but sorting through the *politics* is a more complex matter.

The idea of refundable tax credits, as President George W. Bush has proposed, has thrown the usual political alignments out of whack. Initially there was considerable support for the idea from the more liberal wing of the Democratic Party. Even Reps. Pete Stark (D-California) and Jim McDermott (D-Washington) were attracted to the idea.

Fixed refundable tax credits targeted at the lower-income uninsured would be (in their eyes) a wonderfully progressive approach, especially when compared to the exclusion from taxable income that benefits the employer group market. The exclusion is hideously regressive, benefitting wealthier people with richer benefits far more than it benefits lower-income people with modest benefits. Moving from a regressive tax structure that benefits the wealthy to a more progressive one that helps the low-income is an essential element of Democratic orthodoxy.

On Second Thought

As attractive as refundable tax credits appeared to be, the Left was suspicious that such an idea would be offered by a conservative Republican President. There must be something wrong with the idea ... what could it be? Wait a minute. Of course! How could we be so foolish? A tax credit of $3,000 per family would induce many to purchase health insurance, thereby lowering the numbers of uninsured and gutting the argument for a national health insurance program.

For the Left, the plight of the uninsured is the key argument favoring government-run health insurance. A refundable tax credit would be a dagger in the heart of that long-cherished goal. So even if it means sacrificing a gift of $3,000 a year for low-income families, the Left finds it must put a stop to the tax credit idea.

- First, they've argued it "doesn't go far enough." That has worked in the past on a wide range of issues. Yes, $3,000 is a lot of money, but it's not enough.
- Next, they've rolled out the old "healthy and wealthy" argument—with a twist, because the tax credit is aimed at the poor rather than the wealthy. Call it the "young and healthy" argument. Tax credits might be good for the young and healthy, but how do they help the 62-year-old diabetic?
- Finally, they've challenged the plan for putting people at the mercy of the "evil insurance companies." Far better, the Left argues, to assign them to a kind and benevolent government program like Medicaid than subject them to the vagaries of the market.

Having stumbled on the "evil insurance companies" argument, all that remained for the Left to do was discredit the individual insurance market. They got lots of grants from friendly foundations to prove their case, most often through heartstring-tugging anecdotes about how Betty and Paul were not well served in the individual insurance market.

Of course that approach has put the Left in the awkward position of supporting a regressive employer insurance market that it has been criticizing for at least 20 years. But the hypocrisy will be only temporary, they say. Once they kill the tax credit idea, they expect to get right back to supporting mandates, the Patients' Bill of Rights, and a slew of new regulations because employers can't be trusted to do a good job of providing benefits.

"Pauly and Nichols devote much attention to the broad issue of 'tough choices,' which include the willingness of people to pay more for coverage or to accept restrictions on their coverage."

So, there you have it. For the past year or so we have been besieged by a host of reports and studies claiming $3,000 isn't enough money (it won't pay full cost for a "comprehensive" policy), that it especially won't help the old and the sick (even though most of the uninsured are young and healthy), and that the individual insurance market is mean to some people (even though these people don't appear to be very well served by the employer group market, either). Finally, the studies point out that administrative costs are higher for individual health insurance than they are for General Motors (well, duh!).

The Rest of the Story

The proponents of tax credits have responded early and often to the Left's challenges. Proponents note:

- Tax credits are not intended to pay the full cost of comprehensive coverage; it's hardly fair to attack the idea for failing to do something it's not intended to do.
- Tax credits may not, by themselves, secure coverage for the sickest and poorest of the population, but they could reduce the numbers of uninsured dramatically, by as much as 80 percent.
- People who are "rated-up" (charged a higher premium) or "ridered-out" (excluded from coverage) because of a pre-existing condition can nevertheless get coverage that is of value to them. Such provisions in the individual insurance market encourage people to get coverage while they are healthy, instead of waiting until they become sick.
- Administrative cost comparisons are misleading. Most of the uninsured work for small companies, not General Motors. Moreover, those who make such comparisons fail to consider the possibility of non-employer groups; fail to consider the potential efficiencies of direct sales and Internet marketing; and fail to account for the administrative costs large companies absorb in general overhead.
- Finally, tax credit proponents argue that, if the individual market were provided with the tax advantages of the employer-group market (including a 40 percent tax subsidy and additional subsidies in the form of employer contributions to premiums), there would be a flood of new, actively-at-work, well-subsidized, financially stable, and healthy applicants who would reduce the need for underwriting and risk assessment by carriers.

"As attractive as refundable tax credits appeared to be, the Left was suspicious that such an idea would be offered by a conservative Republican President. There must be something wrong ..."

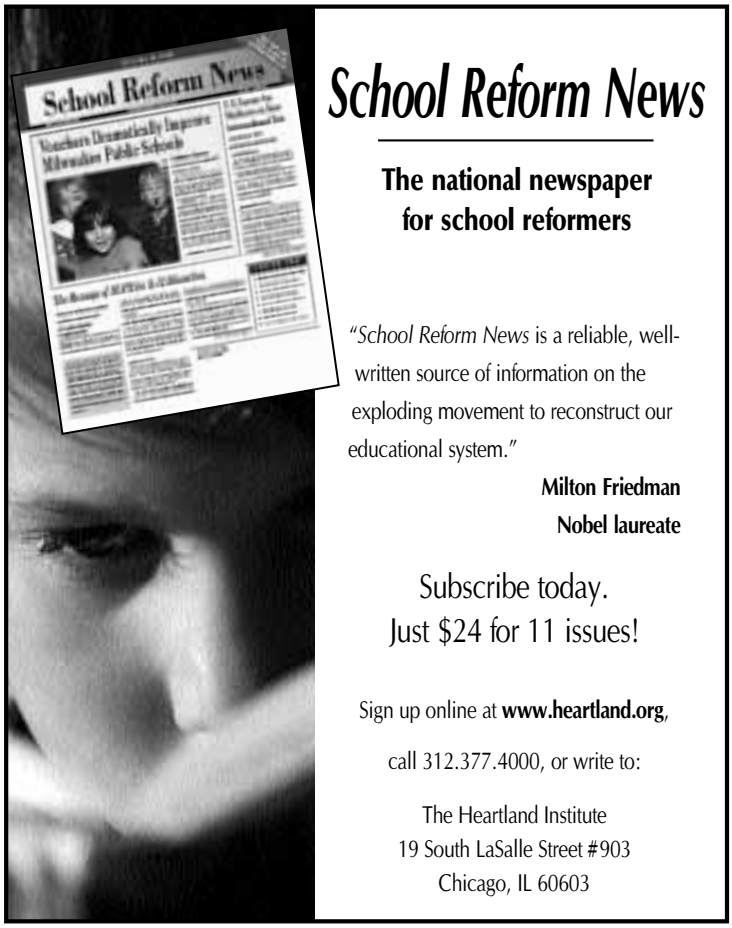
Sorting it Out

In their *Health Affairs* report, Pauly and Nichols sort through the arguments pro and con, identifying those points around which there is agreement and defining the areas where there is disagreement.

According to the economists, the points of widespread agreement include:

- Administrative loads (expenses) are higher in nongroup markets. Typical administrative costs run between 30 and 40 percent of premiums, although that figure seems to be dropping.
- Adverse selection is likely in the nongroup market. People who know they need coverage

CONTROVERSY continued on next page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CONTROVERSY continued

are more likely to buy it than people who feel they do not need it. The problem of adverse selection is most severe in states that impose community rating or guaranteed issue mandates on insurance companies.

- The nongroup market is small and shrinking. Expansions of group enrollment, Medicaid, and SCHIP have drawn people out of the market.
- Policy interventions inevitably produce tradeoffs. Every change in regulation helps some people but hurts others.

There are disagreements around both factual issues and policy judgments. Pauly and Nichols devote much attention to the broad issue of "tough choices," which include the willingness of people to pay more for coverage or to accept restrictions on their coverage. For instance, they discuss exclusionary riders in which coverage is offered except for some specific pre-existing condition.

They make the very interesting observation that some people may discover they are better off not having a condition included in their insurance coverage, because they can afford to pay directly for the services and those cash payments are not subject to the administrative load. So they get full value for the money spent, rather than having 30 or 40 percent removed for insurance administration.

The authors discuss in some detail the difficulty of measuring premium costs, and the risk profiles of covered persons. For instance, they find people known to have chronic conditions are far more likely to "take-up" coverage in both the group and nongroup markets, but the opposite is true for people who self-report fair or poor health status.

Older people are far more likely to purchase nongroup coverage than younger people, at least if they are non-poor (with incomes more than 200 percent of the poverty level).

The authors address a number of other issues as well. The individual market is sometimes criticized for allowing people to customize their benefits, but they note that in the group market satisfaction seems to be correlated with choice. "Having more variety is a benefit that could compensate for having to pay the higher loads in the nongroup market," they write.

Pauly and Nichols also discuss high-risk pools, concluding, "There is some evidence that the presence of a high-risk pool increases the likelihood of private coverage in a state." They are very clear on their opinion of the state-based "reforms" that have been enacted in the past decade, "guaranteed issue and restrictions on allowed premium variance in any form have uniformly reduced coverage in the states that have tried it."

Conclusion

Overall, it appears from the Pauly/Nichols research that the nongroup market does a pretty good job of serving higher-risk people (older and with chronic conditions). If anything, according to the authors, it may do less well at serving younger and healthier people, by failing to adequately identify them and offer coverage at a price they are willing to pay. Nevertheless, the authors write, "the nongroup market produces actuarially acceptable offers for roughly 80 percent of nongroup candidates..."

"The major policy question," they continue, "is this: How can the nongroup market's performance for the unlucky 20 percent be improved without reducing its solid performance for the roughly average-risk 80 percent?"

They conclude, "Our judgment is that the nongroup market is simply ill suited to absorb the sickest fraction of any population, and that forcing market reforms on it for the purpose of enabling it to do so will probably make the overall outcome unacceptable to much larger numbers of people who are using it now than the new policy would help. For the uninsurable, high risk pools or subsidized public coverage are better."

"Our judgment is that the nongroup market is simply ill suited to absorb the sickest fraction of any population, and that forcing market reforms on it for the purpose of enabling it to do so will probably make the overall outcome unacceptable to much larger numbers of people who are using it now than the new policy would help."

MARK PAULY AND LEN NICHOLS

For more information…

WWW The Nichols/Pauly report is available through *PolicyFax*. Point your Web browser to **http://www.heartland.org**, click on the *PolicyBot* icon, and request document **#10745**.

Health Affairs published a dozen papers reacting to the Nichols/Pauly report, written by people with a wide range of viewpoints. All are available on the Web at **http://healthaffairs.org/WebExclusives/Nongrp_TOC.htm**.

A transcript of the October 23, 2002 "Individual Health Insurance: Fact, Opinion, and Policy" conference, sponsored by the Center for Studying Health System Change, is available on the Internet at **http://www.hschange.org/CONTENT/487/?id_conf=12**.

Greg Scandlen is senior fellow in health policy at the National Center for Policy Analysis - Dallas (NCPA) and assistant editor of Health Care News.

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STUDY:

Pill-Splitting Saves Money, Is Safe

BY VICKI LANKARGE

A Stanford University Medical Center researcher said pill-splitting saves money and is likely to be safe and effective with appropriate screening ... even though he didn't specifically study the safety of the procedure.

"When properly implemented, pill-splitting can be a safe, viable cost-saving strategy," noted Dr. Randall Stafford, a researcher at the Stanford Center for Research in Disease Prevention and lead author of an article published in the August 2002 issue of the *American Journal of Managed Care*.

However, the doctor also noted: "In no sense did we look at the specific outcomes of pill-splitting." Stafford said follow-up with patients on the safety of pill-splitting was outside the scope of his study.

Controversy

The study has drawn much attention, driven largely by its potential impact on a pill-splitting lawsuit filed against HMO giant Kaiser Permanente. The suit charges the company endangers some patients' health, solely to enhance profits, by forcing patients who are prescribed smaller-dose pills to accept and cut in half the larger-dose pills.

Kaiser says the lawsuit is without merit. Pill-splitting is purely voluntary, Kaiser representatives say, and encouraged only for a handful of drugs—and even then only for those patients who would not be adversely affected by an imprecise dose. Plaintiffs disagree, contending some patients "are simply provided the double-dose medications and a pill-splitter, often without direction or instruction."

What the Study Finds

Using pharmacy claims data from a Massachusetts HMO with 19,000 members, Stafford and his colleagues examined how often pill-splitting was used. They found the HMO used the practice infrequently and saved only about $6,200 annually.

The researchers then used a screening process to determine which medications were appropriate for pill-splitting, excluding those medications that had time-release formulas or were not in tablet form. Starting with the 256 medications most commonly prescribed both nationwide and within the HMO, the researchers eventually narrowed the list to 11 medications they deemed could be split "safely and effectively with significant cost savings."

Those medications include Lipitor, Paxil, Seerzone, Viagra, Zoloft, and Celexa. They projected the annual savings from splitting these pills could be as high as $259,576 annually for the 19,000-member HMO.

HMOs save money by recommending pill-splitting because the wholesale costs of some medications are exactly the same (or nearly the same) for a larger-dose tablet as a smaller-dose tablet.

For example, 50-milligram tablets of Zoloft, an antidepressant, cost approximately $227 per 100, so it would ordinarily cost an HMO $454 to prescribe 50 milligrams per day with 200 daily doses. But 100-milligram tablets cost about $233 per 100, so the insurer can save $221 in a single prescription by forcing the patient to accept and split the 100-milligram tablets to obtain 50 milligrams per day.

Patients can directly save money on pill-splitting because they are paying only one co-payment for a prescription that lasts, say, two months, rather than paying two co-payments during the same period.

However, mandatory pill-splitting has been condemned by the American Medical Association (AMA), American Society of Consultant Pharmacists, and American Pharmaceutical Association due to the health risks involved. These include the chance patients will divide the pills unevenly and wind up taking incorrect doses. Because some patients suffer from cognitive impairments, they may forget which pills they must split.

"[Researchers] projected the annual savings from splitting these pills [Lipitor, Paxil, Seerzone, Viagra, Zoloft, and Celexa] could be as high as $259,576 annually for the 19,000-member HMO."

The Safety Issue

The study has caused such a stir because both consumers and insurers are demanding relief from skyrocketing health care costs, particularly those related to prescription drugs. Kaiser spokesperson Beverly Hayon said she believes the public's frustration over the high cost of prescription drugs is fueling litigation against insurers. "Pill-splitting is one of the few ways, where warranted, that insurers—and therefore their members—can save money on prescription medicine," she said.

Said Audrey Timmis, an elderly woman who suffers from emphysema who is lead plaintiff in the suit against Kaiser Permanente: "When I tried to split the pills—which were slightly smaller than an aspirin—I usually ended up launching them across the room like tiddly-winks or crushing them into powder between my fingers."

Plaintiff Dr. Charles Phillips, formerly under contract with Kaiser, said the Stanford study is suspect from a safety viewpoint. "The issue is really simple—the split pieces are not equal," he said. "Dosing may range 40 percent between a small and large fragment. This is not modern medicine but rather an experiment in testing the inaction of regulatory agencies. It is bad pharmacy practice."

Stafford said he does not support mandatory pill-splitting. However, he noted that the practice, if done correctly, could help those who pay for prescription drugs out-of-pocket, including the uninsured and some Medicare beneficiaries who do not have prescription drug coverage. For them, pill-splitting "may make newer, more expensive medications available to people who might not otherwise afford them."

"Physicians should consider using pill-splitting with selected medications and patients," said Stafford, a pharma-economist who studies how physicians use medications. "And," he adds, "patients may want to bring it up with their doctors."

Vicki Lankarge is a health care reporter for insure.com, *The Consumer Insurance Guide.*

Comparison Shopping Can Reduce Prescription Drug Prices

BY GREG LACKNER

High prescription drug prices and what to do about them were high on the campaign agendas of candidates across the country, and those issues will likely find their way into legislative proposals at the state and federal level next year. But advocates of having the government "do something" to lower drug prices may be overlooking a far simpler solution.

"A September survey of prescription drug pricing in Missouri discovered consumers can save up to 81 percent on their prescriptions simply by comparison shopping."

A September survey of prescription drug pricing in Missouri discovered consumers can save up to 81 percent on their prescriptions simply by comparison shopping.

The survey obtained prescription prices by calling pharmacies in Jefferson City, St. Louis, and Sedalia in central Missouri. In each city one discount store or supermarket, one chain drug store, and one independent "mom and pop" retailer were chosen. Stores included Tolson Drug, Cordes, Bing's, Walgreens, Medicine Shoppe, Osco, Gerbes, Schnuck's, and Wal-Mart.

Prices were collected for a 30-day supply of one of four popular prescription medications in commonly prescribed dosages, and reflect costs that would be incurred by uninsured customers with no other means of cost reduction.

Among the key findings of the survey:

- Comparison shopping for two generic prescription drugs would save 81 percent;
- Comparison shopping for two brand-name drugs would save an average 9.7 percent;
- The lowest generic prices were spread evenly among supermarkets, chain drug stores, and independent retailers;
- "Mom and pop" drug stores offered significantly lower costs on branded prescriptions.

The survey also discovered a pharmacy that offers a competitive price for one prescription may not offer the best prices for other drugs. For example, three of the nine pharmacies surveyed failed to offer the cheapest price for any of the four prescriptions requested, over half had the most costly price for at least one prescription, and one-third offered both the highest and lowest retail prices for at least one of the four drugs.

"One lesson from this survey is that we don't need more government regulations, bureaucracies, or entitlement programs to reduce the cost of prescription drugs," said Joseph Bast, president of The Heartland Institute, the national research organization that released the survey results. "Instead of pandering to voters by promising price controls and other policies that don't work in the long run, elected officials should simply advise voters to buy prescriptions the same way they buy groceries and appliances: by comparison shopping."

Every once in a while, a problem is actually *smaller* than it appears to be. Consumers could save billions of dollars a year on prescription drugs simply by calling two or three stores and asking for prices before they buy.

The survey was conducted by Public Issue Management, LLP, St. Paul, Minnesota, in September 2002.

Greg Lackner is public affairs director for The Heartland Institute.

For more information…

WWW Complete results of the Public Issue Management Survey are available on The Heartland Institute Web site. Point your Web browser to **http://www.heartland.org**, click on the *PolicyBot* icon, and search for document **#10798**.

A survey conducted by ABC News in Michigan found similar results, available on the Internet at **http://www.detnow.com/news/020722 1204.html**.

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From Inception to Ingestion

How much does it cost to produce a prescription drug?

BY MERRILL MATTHEWS JR.

According to studies cited by the pharmaceutical industry, it costs more than $800 million to move a new drug through the 10- to 12-year discovery, development, and approval process.

But critics claim those estimates are artificially inflated and the actual costs are much lower. For example, Ralph Nader's Public Citizen released a study last year claiming the cost of creating a new drug is only about $110 million (in 2000 dollars). And that includes the cost of failures.

Is there a way to resolve this discrepancy? Yes ... by looking at aggregate research and development spending by the pharmaceutical industry and the number of drugs finally approved.

The Drug Creation Process

The pharmaceutical industry is a high-technology—"pharmatech"—industry that pours billions of dollars annually into new, innovative drugs. But new drugs face numerous hurdles as they move from inception to ingestion ... and those hurdles drive up costs.

Scientists must first identify a chemical compound they think will help a medical condition. They then apply for a patent, which can take a couple of years before being issued. Researchers then must find a deliverable form of the drug and, in most cases, test it on animals.

If animal tests appear promising, the drug will begin moving through the human testing process, a series of three or four clinical trials that may test the drug on thousands of patients at various medical centers across the country, and sometimes internationally.

These trials can take six to eight years, requiring the involvement of thousands of medical personnel. Opportunities for failure abound. Often, it isn't until the end of the clinical trials that enough patients are involved to determine if a drug's active ingredient is effective and the side effects acceptable. Importantly, the patent clock is running all the while, despite the fact the drug isn't yet on the market.

If patients are not responding as researchers had predicted, scientists may be able to adjust the formula, but they sometimes have to scrap the project and start over again, losing the time and the money invested.

If the drug makes it through the clinical trials and demonstrates to researchers it is more effective than placebo (an inactive substance), the manufacturer sends thousands of pages documenting the research to the Food and Drug Administration (FDA) for approval. The FDA review process can take more than two years, though there are ways to expedite it.

According to a 2001 study by economist Joseph DiMasi of the Tufts Center for the Study of Drug Development at Tufts University, for every 5,000 drugs that appear promising enough to be tested in animals, only five make it to human clinical trials, and only one will actually be approved.

The *Wall Street Journal* recently reported that Pfizer spent $71 million researching a "youth pill" intended to stimulate the pituitary gland in hopes of reversing "the physical decline that comes with aging." Early tests on animals seemed very positive, but human trials were not as successful. Pfizer eventually and reluctantly discontinued its research. However, those costs can only be recovered through other drugs that successfully make it through the approval process.

How Much Does it Cost?

It's not easy to determine how much it costs to produce a new drug. Some new drugs are tested on thousands of patients. Others target diseases that afflict relatively few people. Some may go through multiple variations in either animal or human tests before scientists get the right formula.

Moreover, the price of a drug that actually reaches the market must be high enough to recover the cost of those that failed—just as the price of products for sale in retail stores must reflect the cost of damaged, lost, and stolen goods. Otherwise, investors won't be attracted to put their capital at risk searching for the next successful drug.

In 1991, DiMasi and his colleagues published a paper in the *Journal of Health Economics* estimating it cost about $231 million (in 1987 dollars) to take a new drug from creation to approval, including the cost of drug failures and the interest lost had the money been invested rather than used for experiments. A few years later, the Boston Consulting Group (BCG) extrapolated the DiMasi study and concluded it cost about $500 million to get a new drug to market.

BCG recently updated that figure. After interviewing about 60 scientists and executives from nearly 50 companies and academic institutions, the firm concluded it takes roughly $880 million and 15 years to get a single drug to market. According to BCG's report, 75 percent of that cost is drug failures.

The DiMasi study produced for the Tufts Center and released last year also weighed in with a new estimate: the average drug takes about 12 years to move through the approval process and costs $802 million per approved drug.

Another Way to Estimate Costs

Another way to estimate the cost of creating a new drug is to look at total research and development costs—a number that has been tracked for years—and divide that amount by the number of new drugs approved each year, thus yielding the average cost of a new, approved drug. For example, the research-based pharmaceutical companies spent about $26 billion on R&D in 2000, and 27 drugs were approved. Thus, it cost approximately $964 million per drug approved in 2000. (See the accompanying table.)

Of course, this approach is not as scientifically rigorous as the other methods. And cost estimates can vary significantly if many new drugs make it to the finish line in one year, as happened in 1996. Nevertheless, tracking R&D spending and the number of approved drugs over a series of years will provide a relatively accurate estimate of the cost of producing new drugs, as well as help identify cost trends.

This approach also highlights the shortfalls of the Public Citizen study. If drug companies spent only $110 million to get a new drug approved in 2000, including the failed drugs, but spent a total of $26 billion on R&D, then some 236 new drugs should have been approved that year.

Is Innovation Declining?

With only a few exceptions, the number of drugs approved each year has been fairly stable. Of course, some new drugs are intended to capture part of the market of an existing drug. That's just competition, and it has helped to hold prices down. For example, after the launch of a new generation of antidepressants (Prozac) in 1987, the next five antidepressants were introduced at 7 to 45 percent less than the original drug's launch price.

But nothing, not even lower prices, seems to placate the critics. If there is only one patented drug for a specific medical condition, they decry the high price and lack of competition. If there are several drugs treating the same condition, they complain money is being wasted on researching and marketing "me-too" drugs.

Conclusion

Everyone agrees it takes millions of dollars to take a drug through the approval process. The question is how many millions? By dividing the R&D costs by the number of drugs approved in a given year, we can get a rough but accurate picture over time of the money it takes to move a drug from inception to ingestion.

Dr. Merrill Matthews Jr. is a visiting scholar at the Institute for Policy Innovation and assistant editor of Health Care News.

THE COST OF CREATING A NEW DRUG

YEAR	R & D (billions)	Approved/ Year	Cost/Approved Drug (millions)
1987	$5.5	21	$262.0
1988	$6.5	20	$326.9
1989	$7.3	23	$318.7
1990	$8.4	23	$366.1
1991	$9.7	30	$323.5
1992	$11.5	26	$441.1
1993	$12.7	25	$509.6
1994	$13.4	22	$611.3
1995	$15.2	28	$543.1
1996	$16.9	53	$319.0
1997	$19.0	39	$487.4
1998	$21.1	30	$702.0
1999	$22.7	35	$649.1
2000	$26.0	27	$964.1

Source: Pharmaceutical Research and Manufacturers of America

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A DISSENTING VIEW:

Patently Absurd

BY ROBERT M. GOLDBERG

President George W. Bush's proposal to limit the ability of biotech and pharmaceutical firms to protect products from being replaced by generic versions before their patent expires is regarded as a way to speed affordable medicines to consumers. But it is doubtful that the proposal—or more restrictive legislation passed by the Senate—will accomplish that.

Instead, limiting the right to challenge generic firms without curbing the lawsuits required to bring generic products to the market before a patent expires could harm medical progress and the public health.

On the one hand, the Bush proposal recognizes that consuming and discovering new drugs is a good thing. Each generation of new medicines helps reduce total health care spending by billions of dollars. The proposal also recognizes that with rare exception, new uses and forms of innovative drugs provide both a social and a health benefit that satisfies the U.S Patent Office's criteria of being useful, novel, and obviously unique. And it reaffirms that before a generic company can infringe on a valid patent to copy drugs, companies that invent new ones are entitled by law to defend in court an early challenge to each patent by the generic company.

On the Other Hand

But the Bush proposal also caves in to the conventional wisdom that pharmaceutical firms are evildoers and generic firms are defenders of the public good. Contrary to the perception, biotech and drug companies are not getting an extra 30 months of patent life on top of 20 years of protection. In fact, the average "effective" patent life or monopoly for innovators is only 11 years.

Additionally, even with the 30-month stays that are common, the effective patent life is far less than the 18.5 years afforded other industries. In the FTC report, an antidepressant, Paxil, was identified as having five 30-month stays—yet even then it will have less than 15 years of effective patent life.

Current drug-patent law doesn't just allow generic companies to obtain innovator drug trade secrets in order to test, manufacture, and warehouse copycats before a patent ends. It gives the first company to successfully challenge a patent early an incentive to do so: a monopoly of its own. The winner gets 180 days in which no other company can bring a generic competitor to the market.

Generics Drive Lawsuits

In response to an increase in the number of innovative drugs, the number of lawsuits seeking to end patents early soared. During the 1980s only 2 percent of generic drugs tried to cut patent life short as a way to approval. Today, more than 20 percent of all generic drugs now enter the market through legal attacks on patent life. And generic firms are attacking as soon as a drug hits the market, with multiple challenges of the same patent in many cases. No wonder generic companies such as Barr Labs make most of their money not from selling medicines, but from suing drug companies and settling cases. (See "A Bitter Pill," *Fortune*, August 13, 2001.)

It is almost astounding that in this litigation-rich environment the FTC could find only seven products, or eight cases, where innovator companies may have received multiple 30-month stays. The hothouse for trouble is the incentive to sue for early patent termination: the 180-day monopoly of generic drugs. Neither the President's nor the Senate's proposals touch that bonanza in the belief that generic drugs offer, in the words of the FTC, "significant cost savings over brand-name products."

But that assertion is suspect. HMOs and large corporations like using generic drugs because they are cheaper than newer medicines, but that cold calculus fails to look at the total cost of care or the impact on patient health. Studies show patients who were restricted to older, generic asthma and anti-depressant drugs wound up being sicker and spending more on hospitals, doctors, and emergency rooms than those who used newer medicines. Making it easier to bring generic drugs to market might enrich big corporations and HMOs, but it might reduce the number of newer medicines that offer a variety of benefits and fewer side effects to the people using them.

"Making it easier to bring generic drugs to market might enrich big corporations and HMOs, but it might reduce the number of newer medicines that offer a variety of benefits and fewer side effects to the people using them."

Generic Inflation

Finally, generic drugs are not always the bargain the President makes them out to be. For example, a 30-day supply of the generic Prozac is a prescription that costs drugstores just $2.16 or less ... but it can cost anywhere from $72 to $100 at some retail stores.

The generic form of the calcium channel-blocker Vasotec wholesales for about $6. Wal-Mart—a member of a business coalition supporting speedier generic-drug approval—often marks up the drug to the tune of $40.

The President's proposal might make it easier for generic drugs to cut short the patent of new drugs. But don't expect that to lead to better health or significant savings. Instead, as long as the law encourages generic firms to sue early and often to take breakthrough biotech and pharmaceutical products off the market, it will make investing in additional uses and different forms of new medications—which are increasingly more expensive to develop—riskier and costlier still. The 180-day bounty that generic companies and their lawyers pursue must go.

Robert Goldberg is director of the Manhattan Institute's Center for Medical Progress. This analysis appeared October 24 on National Review Online and is reprinted here with permission.

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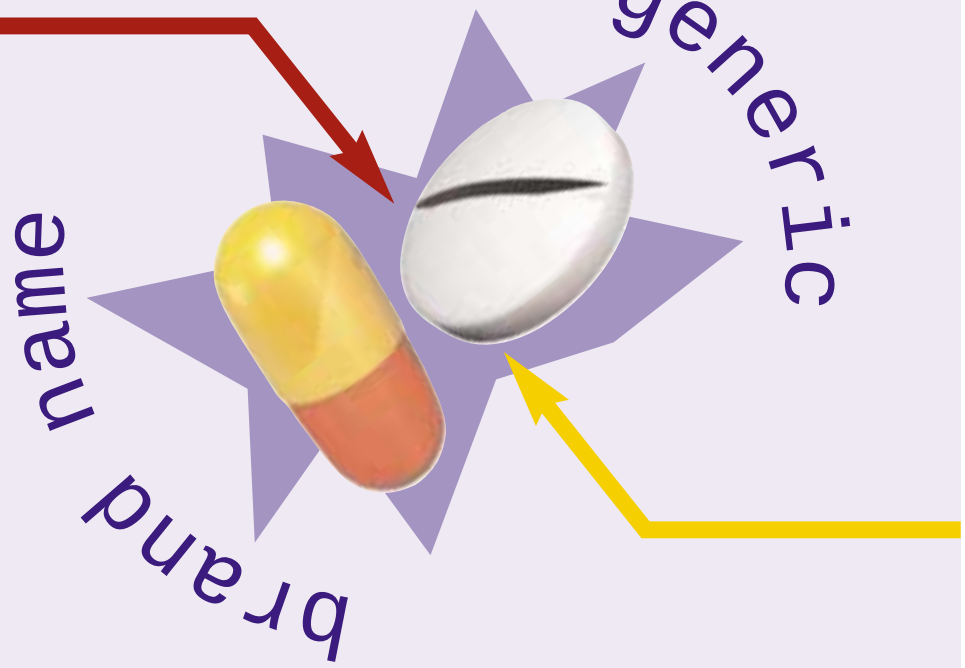


PATENT continued from page 1

provide the FDA with additional information when filing patents, in order to discourage the filing of patents that are not permitted by law.

"Our message to the brand-name manufacturers is clear: You deserve the fair rewards of your research and development; you do not have the right to keep generic drugs off the market for frivolous reasons," Bush said.

Emboldened by FTC Report

Until now, the administration has been reluctant to challenge brand-name pharmaceutical manufacturers by taking direct action on the generic drug issue. The centerpiece of Bush's Rx program to help the uninsured has been a drug discount card, supported by drug manufacturers but opposed by pharmacies and drugstores.

Earlier this year, the Federal Trade Commission concluded an investigation of eight prominent cases in which drug companies used a litigation strategy to delay generic competition on such drugs as Taxol, a chemotherapy drug commonly used for breast cancer, and Paxil, a popular antidepressant. According to administration sources, the President's proposal comes in response to the FTC report, which was published this past summer.

A top Bush official, asking for anonymity, said the administration is confident the action is legally solid. In essence, the President's plan closes loopholes in current patent law that allow the big brand-name drug manufacturers to use the courts to delay generic competition once the patent has expired on one of their blockbuster drugs.

Reaction

Tom Miller, director of health policy studies for the Cato Institute, was cautiously optimistic about the results the Bush plan might achieve. "The proposed regulation will curb the current handful of abuses of the patent process for prescription drugs," Miller noted, "without undermining broader incentives for innovative research. We need to maintain a balance between encouraging lower drug prices through generic competition and ensuring that brand-name manufacturers will continue to create new lifesaving drugs."

Health insurance administrators, AARP officials, many Republicans, and the generic drug industry were more effusive in their praise for the new proposal, according to the *Washington Post*. The *Wall Street Journal* reported Governor William Janklow (R-South Dakota) as predicting, "This is going to save the public a lot of money."

Nevertheless, some legislators criticized the President for issuing the rules shortly before last month's midterm elections. Rep. Richard Gephardt (D-Missouri) called the announcement a "cynical election-year ploy" intended to attract the votes of seniors facing high prescription drug costs. Senator Tom Daschle (D-South Dakota) said the proposal contains "loopholes and omissions" and has inadequate enforcement mechanisms.

The Bush plan was also criticized for omitting provisions contained in a bill (S. 812) passed in July by the Senate but never approved by the House. The Senate bill includes language giving generic drug makers the right to sue a brand-name manufacturer who files new patents solely to prevent competition. It would also require brand-name makers to file any suits against generic competitors within specific time limits. Sen. Charles Schumer (D-New York), a sponsor of the Senate legislation, said Bush's proposal "closes one door to the pharmaceutical industry in their attempt to delay generics, but it opens up several others."

Jake Hansen, vice president of the generic drug company Barr Laboratories, said the new regulations "would probably take care of 70 percent of the problems addressed in the Senate bill."

The brand-name pharmaceutical industry had few comments following the announcement. Jeff Trewitt, a spokesperson for the Pharmaceutical Research and Manufacturers of America (PhRMA), merely said the proposal was "complex" and would be reviewed.

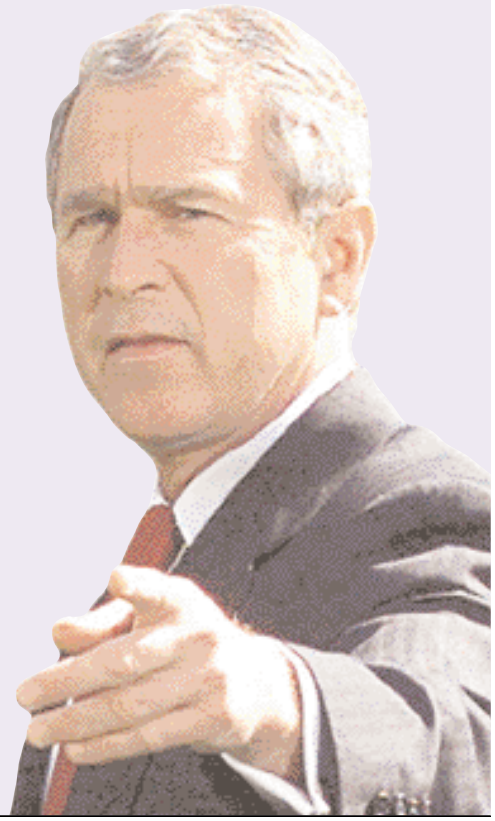
Several attorneys representing brand-name drug companies predicted the industry would file suit opposing the new Bush rules. In a story from the *Washington Post*, Marc Scheineson, a former FDA official now specializing in food and drug law, said although the White House appears to be on solid legal ground, the incentive for the industry to litigate is enormous.

The Cato Institute's Miller urged the administration to improve on the plan by focusing on bigger issues. "Instead of focusing too narrowly on opportunistic short-term fixes," he said, "we should also reexamine other factors that push drug prices higher: the burdensome FDA drug-approval process that delays entry of innovative products and limits competition, and the excessive growth of third-party insurance coverage of prescription drugs that desensitizes individual consumers to the full cost of their spending decisions."

Conrad F. Meier is managing editor of Health Care News.

"Our message to the brand-name manufacturers is clear: You deserve the fair rewards of your research and development; you do not have the right to keep generic drugs off the market for frivolous reasons."

PRESIDENT GEORGE W. BUSH



For more information…

WWW The new rule was published in the *Federal Register* on October 24, opening a 60-day public comment period that closes December 23. The complete text of the new rule and information about how to submit public comments are available on the Internet at **http://frwebgate5.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=2241516857+0+0+0&WAISaction=retrieve** (HTML) or **http://frwebgate5.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=2241516857+0+1+0&WAISaction=retrieve** (PDF)

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OREGON continued from page 1

voters still undecided. Mark Nelson, who managed the campaign against Measure 23, considered the poll a reflection of the public's general frustration with rising costs and decreasing control over their health care.

Nevertheless, on Election Day voters said they were not ready to take a chance on sweeping change. "I think people are concerned about access to health care and the cost of health care, but they don't want to throw the baby out with the bath water," said Nelson. "They see a system they believe needs to be constantly reformed and modified, but not by throwing it entirely out the window."

HIAA's Young touted the Oregon results as an endorsement of free-market health care and rejection of government interference in health care decision-making. "The voters of Oregon decided overwhelmingly that private health insurance, offered primarily through the workplace, gives people better access to quality medical care, as well as greater control over the health decisions affecting their families, than would the government-run, one-size-fits-all proposal resoundingly rejected at the polls."

"Measure 23 ... attracted just 204,082 votes, 21 percent of the total, while 786,768 voters—79 percent—rejected the plan."

Red Ink Likely

Measure 23 would have created a state government-run health plan covering 100 percent of Oregonians' "medically necessary" health care costs, requiring of them no deductibles and no out-of-pocket payments. Prescription drugs, preventive care, mental health services, long-term care, dental and vision care, and many alternative therapies would have been fully covered.

The proposal's operating fund would have been financed by a personal income tax increase capped at 8 percent and employer taxes assessed at 11.5 percent of payroll; redirection of current state and federal funding for Medicare and Medicaid to the single-payer plan (a diversion never approved by the Centers for Medicare and Medicaid Services); and elimination of the state workers' compensation system.

According to research conducted by the Legal and Economic Consulting Group in Wayne, Pennsylvania, the Oregon plan would likely have led to increased taxes, substantially higher medical costs, and fewer health benefits than most Oregonians now enjoy, a result of cost-containment measures sure to be employed.

The study, commissioned by the American Association of Health Plans (AAHP), estimated the Oregon single-payer proposal would have required additional annual revenues of $14.5 to $21.4 billion over and above current state expenditures on health care—some $4,000 to $5,900 per individual and $10,000 to $15,000 per household.

The payroll and income tax increases permitted under Measure 23 would have raised approximately $11 billion—creating an estimated shortfall of at least $3.5 billion. The shortfall, according to the consulting group, could have been as much as $10 billion if higher payroll taxes caused some businesses to reduce investment in the state and some citizens to relocate to lower-taxed states.

Clinton Deja vu

Notwithstanding the Legal and Economic Consulting Group's analysis, Measure 23 was endorsed by government and private-sector labor unions, senior citizen lobbying organizations, community activist groups, and representatives of the Democratic and Green Parties ... not only in Oregon, but also from Washington, California, and as far away as Massachusetts. All saw the Oregon measure as an important foot in the door for single-payer health care.

Dr. Harvey Frey, director of the Health Administration Responsibility Project in California, urged his members to send money to the campaign regardless of whether they lived in Oregon.

In July, a single-payer advocacy group called Health Care 2000, headquartered in Washington state, voted to change its name to Health Care for All-Washington, aligning themselves with Health Care for All-Oregon and Health Care for All-California. The groups have joined Health Care Is a Right, a national coalition planning a March 2003 conference to explore launching a ballot initiative advocating universal health care in the city of Seattle.

Single-payer proponents, silent for nearly a decade, believe the political landscape may have changed substantially since former President Bill Clinton's Health Security Act was rejected in 1993. Going into the November 5 election, supporters of Measure 23 in Oregon felt that even if it failed to pass, a "good showing" could provide the momentum needed to pursue additional efforts on the state and federal levels.

It would be difficult, of course, for all but the most ideological supporters of single-payer health care to see the November 5 results as a "good showing." Health Care for All's Lindgren did his best in "post-election thoughts" posted on the group's Web site, noting "Our campaign has given fresh hope and excitement to health care activists around the U.S."

Blaming Markets

Oregon's advocates of socialized medicine, like their counterparts in other states, blame "market failure" for rising health care costs, the loss of patients' rights, waste, and fraud. But many experts say previous government interventions, similar to those now being proposed, are largely responsible for the current dysfunctional health care market.

Over the years Oregon passed benefit mandates and regulations that have crippled the private health care marketplace. The state's patients' bill of rights law, mental health parity law, guaranteed issue and community rating laws, and hundreds of unfunded benefit mandates have made Oregon one of the most over-regulated health care and health insurance markets in the nation.

This toxic regulatory climate has driven many private insurers out of the state and encouraged many people to remain without health insurance until they need it. This has caused health insurance premiums to soar, resulting in some 400,000 uninsured citizens.

Leap of Faith

Supporters of socialized medicine also face a task made more difficult by growing public awareness of the idea's failure in other countries. Canada and England have long waiting lists, limited access to new technology, and weak domestic pharmaceutical industries. They are now moving to privatize their health care systems.

Members of Health Care for All-Oregon claim with sufficient funding, their state can do what other countries have never done before: socialize the cost of health care without needing to impose price controls and other kinds of rationing.

At best, the single-payer system would have resembled the managed care system Oregonians say they hate, but without the innovation and accountability that come from competition. At worst, their plan would resemble Medicare, which seniors rightly complain about all the time.

"Oregonians made the right choice by rejecting a single-payer system," said Twila Brase, president of Citizens' Council on Health Care, a Minnesota-based policy organization. "The approval of a government health care system *for* all citizens would have signaled the beginning of health care rationing *to* all citizens. Rationing is implicit in any government health care system. One need only look at Medicare, America's single-payer system for senior citizens," she warned.

Conrad F. Meier is managing editor of Health Care News.

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Merrill Matthews Jr., Ph.D., is a Heartland Senior Fellow specializing in health care policy and a visiting scholar with the Institute for Policy Innovation. Dr. Matthews is past president of the Health Economics Roundtable for the National Association for Business Economics, the largest trade association of business economists, and health policy advisor to the American Legislative Exchange Council, a bipartisan association of state legislators.

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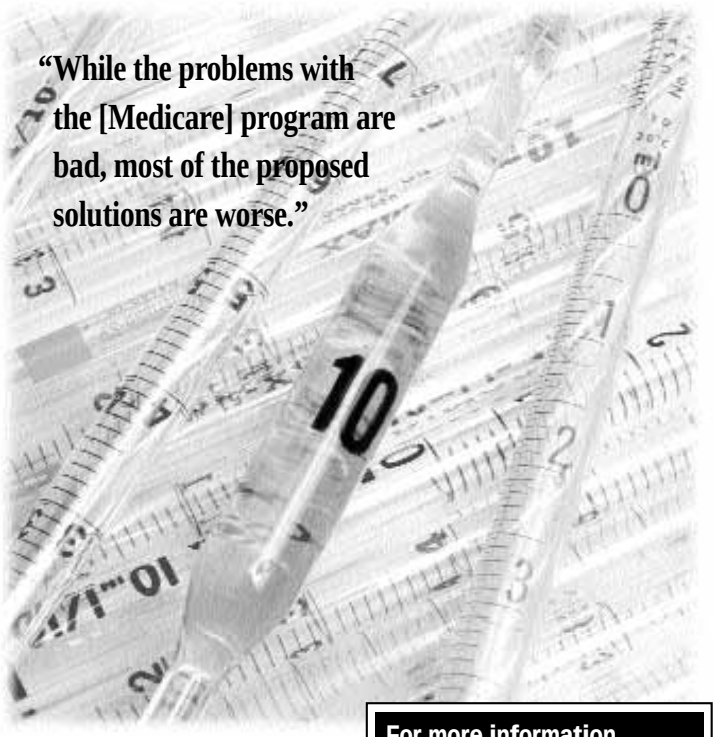
Ten Principles to Guide Medicare Reform



BY JOHN GOODMAN, ROBERT GOLDBERG, AND GREG SCANDLEN

Politicians of both major parties are endorsing ill-considered schemes to add a prescription drug benefit to Medicare. While the problems with the program are bad, most of the proposed solutions are worse.

Medicare deserves thoughtful reform—reform that can greatly reduce senior citizens' exposure to catastrophic prescription drug costs, improve overall health care quality, and control taxpayer costs. What follows are 10 principles to guide that reform.

PRINCIPLE #1
Medicare needs fundamental reform

Despite its popularity, Medicare violates almost all principles of sound insurance. It pays too many small bills the elderly could easily afford on their own, while exposing them to thousands of dollars of potential out-of-pocket expenses, including the cost of most of their drugs. Seniors are the only people in our society who have to buy a second health plan to fill the gaps in the first. But even with Medicare and Medigap insurance, most do not have the same drug coverage non-seniors have.

Some proposals would keep the basic structure of Medicare intact but add a new drug benefit. That approach would be wasteful and inefficient ... not to mention it would create enormous taxpayer burdens in future years.

PRINCIPLE #2
The failure to cover prescription drugs creates incentives to substitute more costly therapies

Dollar for dollar, drugs offer a better return on health care spending than do other major therapies. Yet Medicare's practice of covering very few prescription drugs encourages doctors and their elderly patients to choose physician and hospital services over less costly, more appropriate drug therapies.

PRINCIPLE #3
The plan that administers drug benefits should be the same plan that administers other benefits

When two health plans administer two different sets of benefits, the decision-makers can avoid the full costs of their bad decisions and cannot reap the full benefits of their good decisions.

Suppose one plan controls hospital benefits and another controls drug benefits. Given a fixed premium for each, the incentive of the first plan is to reduce hospital costs. The incentive of the second is to reduce drug costs. Neither plan has an incentive to consider the overall picture and maximize the health benefits of a given money outlay. The solution is to have a single health plan making all treatment decisions.

PRINCIPLE #4
Paying one premium to one plan is much more efficient than paying several premiums to several plans

When seniors purchase Medigap insurance to reduce their exposure under Medicare, the federal government requires that insurance to cover the Part A and Part B deductibles and co-payments. Thus, seniors with Medigap insurance have first-dollar coverage for many medical services, even though they may lack drug coverage. The result is a great deal of waste. Health economists estimate seniors with both Medicare and Medigap insurance spend about 30 percent more on health care than those with Medicare alone.

Some propose creating a third plan with a separate premium to cover drugs. For most seniors, this would mean three premiums for three plans. But that approach would compound the problems of the current system. What is needed is not three premiums for three plans, but one premium for one plan—a plan similar to the health coverage most non-seniors have.

PRINCIPLE #5
Adding a drug benefit to Medicare, as it is currently structured, would create an unbearable burden for future generations

Medicare currently pays only about 5 percent of the cost of the prescription drugs used by Medicare beneficiaries. Proposals to add a comprehensive prescription drug benefit to the program could shift as much as two-thirds of senior drug costs to Medicare. Such a benefit would increase the already-substantial burden Medicare will create for future taxpayers:

- Even without reform, 48 percent of federal income tax revenues will be needed to meet the annual deficits in Social Security and Medicare by the year 2050—in addition to the 15.3 percent payroll tax.
- Under the House Republican proposal, 55 percent of income tax revenues will be needed just to pay seniors' benefits by the time today's teenagers reach retirement age.
- Under the House Democrats' proposal, more than two-thirds of income tax revenues will be needed just to pay seniors' benefits by mid-century.

> **"Virtually all of Medicare's shortcomings stem from the fact that Medicare's features have been determined by politicians, not by firms that must compete for business by pleasing their customers."**

PRINCIPLE #6
A reformed Medicare could cover prescription drugs without any increase in taxpayer subsidies

Add the amount Medicare spends on the average beneficiary each year to the amount seniors are already paying for the most popular Medigap policy and the combined sum should be enough to buy the same kinds of health insurance coverage the non-elderly now have, including prescription drug coverage (assuming the private plans can pay Medicare rates). That is the conclusion of an NCPA study by Milliman & Robertson, Inc., the nation's leading actuarial firm on health benefits.

PRINCIPLE #7
A reformed Medicare should have different levels of cost sharing for different drugs

Almost all proposals to add a prescription drug benefit to Medicare establish a uniform level of cost sharing for all drugs—regardless of the drug and regardless of the condition it is supposed to treat. Yet an insurance plan with this feature makes little economic sense. Just as some general health care services are more discretionary than others, some drugs are more discretionary than others. And when patients exercise greater discretion, less waste and better outcomes will result if patients bear a larger share of the bill.

PRINCIPLE #8
By using Medical Savings Accounts, seniors could control drug costs as well as or better than under managed care

Managed health care plans in general have attempted to hold down their drug cost increases by using pharmacy benefit managers (PBMs) to negotiate discounts with pharmacy chains, limit coverage to lower-price generic drugs instead of patented, brand-name drugs, and encourage the use of prescription drug therapies only if the benefits to the patient's health appear to justify the added cost.

For more information…

WWW This article is an executive summary of "Medicare Reform and Prescription Drugs: 10 Principles," *NCPA Policy Report No. 256*, issued in October 2002 by the National Center for Policy Analysis. The full text of the 30-page report is available through *PolicyBot*. Point your Web browser to **http://www.heartland.org**, click on the *PolicyBot* icon, and search for document **#10746**.

PRINCIPLES continued on next page

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PRINCIPLES continued

Yet one study found that restricting seniors' access to pharmaceuticals was associated with more emergency room admissions, hospital stays, and doctor visits for such illnesses as depression, heart disease, ulcers, and diabetes. The elderly were twice as likely to be harmed by these restrictions as were people under age 65.

An alternative approach has been taken in South Africa, where patients with Medical Savings Accounts (MSAs) are controlling drug costs as well as managed care, but without the cost of managed care. In one plan, per-member-per-month costs for drugs were 27.6 percent higher when patients were spending insurance company money than when they were spending their own money from MSA accounts.

PRINCIPLE #9

Under a reformed Medicare, seniors should have access to the same health plans as non-seniors

Virtually all of Medicare's shortcomings stem from the fact that Medicare's features have been determined by politicians, not by firms that must compete for business by pleasing their customers. Dollar for dollar, health plans designed in the marketplace will almost always be superior to plans designed by politicians.

Like for-profit firms, politicians must compete to survive. But the nature of that competition forces them to weigh political costs against political benefits—where "costs" and "benefits" are measured in terms of impact on the next election. Private firms competing in a marketplace, by contrast, must compare economic costs with economic benefits. Our ultimate goal should be to enroll seniors in the same plans to which non-seniors have access.

PRINCIPLE #10

Under a reformed Medicare, health plans should not have incentives to over-provide or under-provide care

In designing a reformed Medicare, we must be careful not to give health plans incentives to under-provide to the sick and over-provide to the healthy. An ideal structure is for seniors to have long-term enrollment in a health plan so they can establish long-term relationships with physicians and health care facilities. During the contract period, enrollees could switch health plans at any time. However, a switch of plans would require the consent of both the acquiring and the departed plan, and this would almost always necessitate a lump sum payment from one plan to the other.

In such a system, health plans would have an incentive to compete for the sick, rather than to avoid them. Plans would also have an incentive to specialize in certain kinds of care, e.g., cancer care or treatment of heart disease.

Following these principles would not solve every problem afflicting the Medicare program. But adhering to them would keep policy makers from creating problems that are even worse than the problems they are trying to solve.

John C. Goodman is president of the National Center for Policy Analysis, and Greg Scandlen is its senior fellow in health policy. Robert Goldberg is a senior fellow at the Manhattan Institute, researching, writing , and lecturing on health care issues.

Cost-Shifting Hides True Cost of Government-Run Health Care

BY HON. FRANK LASEE

How do we ensure that Americans have access to the health care they need, encourage innovation and research, and still contain costs?

Nanny Mentality

The first answer from many people, including government bureaucrats and elected officials, is often to have the government "do something." That's unfortunate, because the government has already caused the very problems it is being asked to solve.

Over the past decade, Medicare and Medicaid have been steadily growing as a share of total health care spending. According to the Centers for Disease Control and Prevention, Medicare expenditures grew from 17.3 percent of total health care spending to 20.6 percent between 1991 and 1998. Medicaid grew from 13.2 percent to 15.7 percent over the same period. This means more than one-third of all health care costs in 1998 were paid for with tax dollars.

Why has government-funded health care grown so much? Mandated services and expanded eligibility, for a start. Health care for 10 people costs more than health care for eight people. Putting more people into government-funded health care and giving them more services means the government will spend more money.

Moreover, giving more people access to more services increases demand, which places greater upward pressure on prices. As prices rise, legislators find themselves in a quandary: how to continue offering increasingly expensive services to an increasing number of people without bringing on the wrath of the taxpayer.

Non-Solution

Medicare and Medicaid pay according to a list of maximum prices for specific services, but these cost-control prices don't reimburse health care providers for their full expenses. According to a Lewin Group study, Medicare reimbursed Wisconsin hospitals for only 89 percent of the cost of services provided to Medicare patients in 1999. Medicaid was worse, reimbursing Wisconsin hospitals for only 78 percent of their costs (not prices, but costs) in 1999.

Nationally, Medicare reimbursed 100 percent of hospital costs (according to the Lewin study), but 33 states were under-reimbursed—Medicare paid less than the cost of providing services. Medicaid paid 96 percent of hospital costs nationally and under-reimbursed 41 states.

Less Access

Wisconsin is experiencing a shortage of dentists, because Medicaid reimbursement rates are so low (under 70 percent of costs for dentists) and come with so many bureaucratic strings attached as to discourage participation in the program.

Last August, the largest pharmacy chains in Massachusetts declared they would stop filling Medicaid prescriptions due to under-payment for those products.

"Because health care providers take a loss on government programs, they make up for it by charging private payers—individuals and private insurers—more."

Low reimbursement rates are driving up the overall cost of health care, making it less affordable for the rest of us, and thus less available for more people. The predictable consequence is less care for more people, the exact opposite of the program's purpose.

Other People's Money

The owners of a neighborhood grocery store give their regular shoppers a discount, and generally lose money on those transactions. To make up for it, they put higher prices on everything, so other customers pay more. That's cost-shifting.

Because health care providers take a loss on government programs, they make up for it by charging private payers—individuals and private insurers—more.

As insurance premiums rise some individuals are priced out of the free market, unable to pay the inflated prices and forced into some manner of government program.

The cost-shift also affects the small business owner. Since the owner can no longer afford to pay all or even part of the premium, more of the cost is shifted to the employee ... or the employer simply discontinues coverage altogether.

Health Care Pork

Cost-shifting by Medicare and Medicaid is a hidden tax paid by everyone in one way or another.

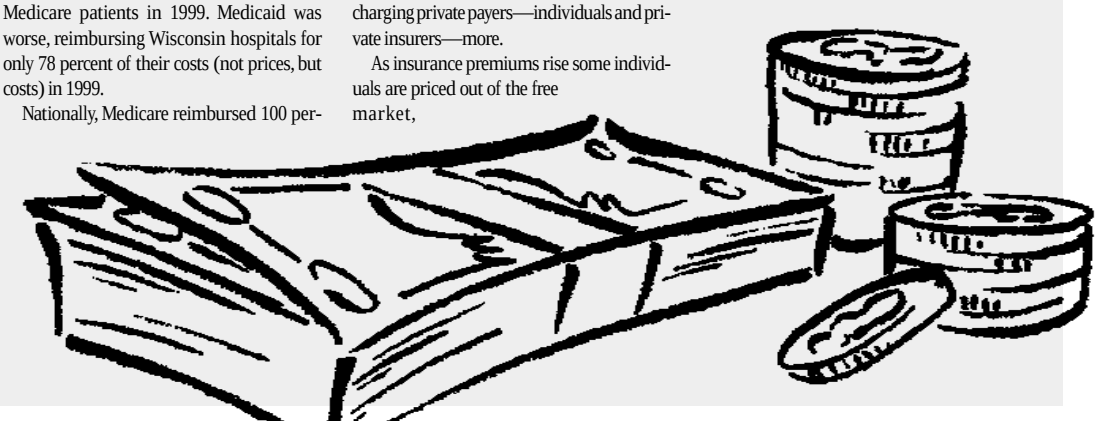
The reason cost-shifting exists, and the reason it is likely to continue to exist, is purely political. Promising greater health care benefits is just another form of pork: vote for me, and you'll get more.

Politicians know, of course, that they need to contain the costs of their programs: Health care is a major issue with voters, but so are taxes. The insidious lie in all this is that we taxpayers are still paying directly with our tax dollars, indirectly through cost-shifting, and even more indirectly by the rationing of health care services.

Paying higher reimbursement rates would cost more from a direct government standpoint. Increasing reimbursements to 80 percent of billed costs, for example, would increase the cost of Medicaid in Wisconsin by more than $311 million in state money, and $463 million in federal money.

Officials at the state and federal levels would be doing themselves and their constituents a favor by admitting what many already know: The current policies of underpayment and cost-shifting are hurting more than they are helping. Instead of trying to provide the services and hide the true costs, government officials should tell taxpayers just how much they're really spending. Then we can make real decisions, based on real information.

State Rep. Frank Lasee represents the 2nd Assembly District in Wisconsin. He can be reached at 608/266-9870 or email Rep.Lasee@legis.state.wi.us.



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State Legislative UPDATE

COMPILED AND EDITED BY CONRAD F. MEIER

A MONTHLY REVIEW OF STATE LEGISLATIVE ACTIVITY

ARKANSAS

Arkansas Governor Mike Huckabee (R) says state officials will begin promoting Eli Lilly's and Pfizer's prescription drug discount cards to low-income residents who are eligible for Medicare and lack prescription drug coverage.

According to Huckabee, as many as 100,000 Arkansans could be eligible for the drug cards. Fewer than 7,000 state residents currently have Pfizer's card, and about 2,000 have Lilly's card, officials from each company said. Huckabee said an $80 prescription drug would cost $12 with Lilly's card and $15 with Pfizer's.

To qualify for the cards, state residents must be eligible for Medicare, have no prescription drug coverage, and earn less than $18,000 annually for an individual and $24,000 for a couple.

MASSACHUSETTS

Massachusetts officials scaled back a plan to cut Medicaid payment rates to pharmacies, ensuring that at least two of the state's largest pharmacy chains—Walmart and Osco—would continue to serve the state's 900,000 Medicaid beneficiaries.

But the state's three largest pharmacy chains—CVS, Brooks Pharmacy, and Walgreens—announced they would discontinue their participation in Medicaid unless the state increases the reimbursement rate.

MISSISSIPPI

The Mississippi legislature approved a measure that would cap awards in malpractice lawsuits against physicians, hospitals, and nursing homes, ending a long standoff between House and Senate negotiators. The House voted 88-31 and the Senate 41-6 to limit jury awards for non-economic damages to $500,000. That figure would be raised to $750,000 in 2011 and $1 million in 2017.

The legislation also requires that malpractice suits be filed in the county in which the alleged malpractice occurred; doctors or nurses who volunteer their services would be immune from malpractice lawsuits; the statute of limitations in cases against nursing homes would be reduced from three to two years; and a doctor who is listed among multiple defendants must be found to be more than 30 percent at fault to be held responsible for up to 50 percent of the final jury award.

Although the legislation does not include a proposal requested by Governor Ronnie Musgrove (D) that would have created a state-administered malpractice insurance pool, the governor is expected to sign the bill.

NORTH CAROLINA

The state supreme court refused to hear an appeal from North Carolina officials to block a lawsuit alleging the state's Medicaid program does not provide adequate dental care to low-income children.

In the lawsuit, filed in November 2000, representatives for six children said they and other Medicaid beneficiaries in the state must conduct extensive searches and travel long distances to find dentists who will treat them. About 16 percent of North Carolina dentists participate in the state's Medicaid program, one of the lowest participation rates nationwide.

All but one of the original six children who filed suit has dropped out of the lawsuit. Eight new plaintiffs promptly replaced them.

Lawyers for the state argue Medicaid recipients unhappy with government benefits cannot file suit against the program. The court decided without comment not to hear the state's appeal.

Massachusetts officials scaled back a plan to cut Medicaid payment rates to pharmacies, ensuring that at least two of the state's largest pharmacy chains—Walmart and Osco—would continue to serve the state's 900,000 Medicaid beneficiaries.

OREGON

Measure 23, sponsored by Health Care For All-Oregon, failed in the state's November ballot by a 79 percent to 21 percent margin. (See story on page 1.) The measure would have required the state to implement a single-payer health care system covering all medically necessary health services, including preventive care, prescription drugs, long-term care, and alternative care, by 2005.

Businesses would have paid a new payroll tax of as much as 11.5 percent and personal income tax rates would have increased by as much as 8 percent. State officials estimated the measure would have cost about $19 billion per year.

The *New York Times* reported voters appeared receptive to opponents' arguments that the proposal was too costly, was likely to harm employers, and might drive doctors from the state.

RHODE ISLAND

State officials have moved to block reimportation of less-expensive prescription drugs from Canada in response to the increased number of state residents who illegally order treatments from Canadian pharmacies. State law requires out-of-state pharmacies to register for a license with the state Board of Pharmacy before they can market treatments to state residents, and federal law prohibits the importation of prescription drugs across the U.S. border. (For more information on drug reimportation, see "Rx Reimportation: A Legislative History," *Health Care News*, November 2002.)

But the state pharmacy board has no authority over Canadian pharmacies, and the federal government cannot monitor the estimated two million packages of medications sent across the border each year.

After a Rhode Island physician informed the state pharmacy board some of his patients had ordered treatments from two Canadian pharmacies, the board sent the pharmacies cease-and-desist orders and informed Canadian regulatory authorities of the state licensure requirement.

In response, Ronald Guse, registrar of the Manitoba Pharmaceutical Association (MPA), informed pharmacies in the province they must have a license from Rhode Island to market prescription drugs in the state.

According to Guse, MPA rules mandate pharmacies in the province cannot violate laws in the jurisdictions where patients reside. Catherine Cordy, head of the Rhode Island pharmacy board, said Canadian pharmacies do not qualify for a license to market prescription drugs to state residents because exportation of the treatments to the United States violates federal law.

TENNESSEE

State Representative Kathryn Bowers (D) wrote a letter to Governor Don Sundquist (R) requesting the state delay the planned termination of benefits for about 95,000 people enrolled in TennCare, the state's troubled Medicaid managed care program.

The reduction in services results from a waiver, approved earlier this year by the federal government, that allows the state to restructure eligibility and benefits offered under TennCare.

The waiver requires TennCare to reverify all non-Medicaid-eligible beneficiaries' eligibility. Some 159,000 current beneficiaries are expected to be found ineligible under the new guidelines, according to state officials.

TennCare spokesperson Lola Potter said she did not know if the state would extend the reverification process and would have to look to the governor for leadership.

VIRGINIA

State health advocates protested potential funding cuts of 5 to 15 percent to the state's mental health system this fiscal year and next to counter a projected $2 billion state budget deficit.

Governor Mark Warner (D) has said every state agency "should expect cuts of 5 percent at least" during the first round of state spending reductions.

But mental health advocates said the cuts could have "frightening consequences for a mental health system that is already stretched."

Delegate Phillip Hamilton (R), chair of the House Health, Welfare and Institutions Committee, said, "We can't afford to take mental health off our priority list. It can't afford any more budget reductions."

WEST VIRGINIA

Governor Bob Wise (D) mailed letters to drug makers Merck, GlaxoSmithKline, and other companies requesting they offer West Virginians the same medication prices charged in Canada. Wise said residents of other countries pay much lower prices. "We want West Virginians to pay the same price as the people in Canada."

According to Wise, the arthritis treatment Celebrex costs between $78.00 and $93.09 a month at local pharmacies, while the drug costs $46 per month in Canada. Wise called on pharmaceutical companies to make a "good faith effort" in negotiating drug discounts associated with the Golden Mountaineer Card, the state's drug discount card for seniors.

The State Legislative Update is compiled from a wide range of news sources, including the Council for Affordable Health Insurance (CAHI) http://www.cahi.org; *the National Association of Health Underwriters (NAHU)* http://nahu.org; *Bizjournals at* http://bizjournals.com; *Stateline at* http://stateline.org; *and Lexis/Nexis research.*

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The Galen REPORT

GALEN INSTITUTE

A monthly review of health policy matters

I was invited by Miles Cole of the Maryland Chamber of Commerce to speak about Health Reimbursement Arrangements (HRAs) at a public hearing before the Maryland Health Care Commission in Baltimore.

Reception to the idea by this government agency was markedly different than in my talks with doctors in Ocean City and insurers in Salt Lake City.

The Maryland commission is conducting its annual review of the comprehensive standard health benefit plan all small employers providing health insurance in the state must offer. The Chamber thought it would be a good idea for the commission to hear about the new HRA consumer-driven health plan option.

I provided a package of materials including an excellent description of HRAs prepared by the Employers Council on Flexible Compensation and a detailed description of the new HRA offering for federal workers by the American Postal Workers Union.

Concerns: To put it mildly, commission members had many concerns about HRAs. Commissioner Ernie Crofoot, who repeatedly implied his support for a single-payer system, said he believed: 1) People will forgo care to save money, and 2) HRAs would lead to the very adverse selection the small group market reforms were created to address 10 years ago.

I responded that most of the HRA plans are incorporating generous incentives for people to get screening and other diagnostic tests, immunizations, etc. Also, it is penny wise and pound foolish for people to forgo care since they will pay in poorer health and more expensive care later on.

Also, people with more health problems are likely to find attractive a plan that allows them maximum choice of physicians through their spending account. Once they trigger the catastrophic insurance threshold, they have good fee-for-service insurance.

Too Complicated? Executive Director Barbara McLean said, "Do you really think small business owners can organize something this complicated?" I suggested they are very motivated to find some way to control costs, and many find it appealing to offer a product that engages consumers as partners in saving money on health care. I also believe the market would organize itself to make the HRA offering relatively simple for small businesses to administer.

Acceptance: Another senior staffer of the commission asked, "Why would HRAs work when only one company in Maryland is offering MSAs, and MSAs and HRAs are virtually the same thing?"

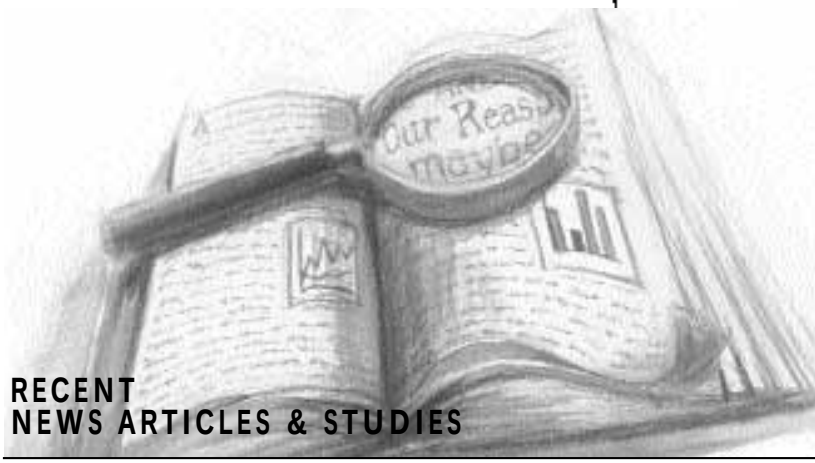
First, I noted, Maryland makes it almost impossible to offer MSAs because of its comprehensive benefit package requirement; second, HRAs have many fewer dictates from government about how they can be shaped; and third, HRAs have a much bigger potential market, making it worthwhile for companies to invest in creating this new product.

Competition: Commission members did express their concern about how little competition there is in the small group health insurance market in Maryland. Witness after witness said competition would bring down prices. Commissioner Crofoot suggested the only solution he sees is a single-payer system. (He was, by the way, very distressed that a union would be offering the HRA plan to federal employees, believing they must have been tricked.)

As an aside, I was surprised to see that Dr. Lynn Etheredge of George Washington University's Health Insurance Reform Project is a member of the commission. He brought both insight and knowledge to the discussion.

My conclusion: Government officials are not very receptive to new ideas, especially ideas that would empower consumers. Especially in Maryland. The commission decided on October 17 that HRAs would not be available as an option in the state's standard benefit program. Companies operating under ERISA could still choose the HRAs, as could clever small businesses operating outside the state's mandated benefit program.

Grace-Marie Turner



RECENT NEWS ARTICLES & STUDIES

Association Health Plans

Greg Scandlen
National Center for Policy Analysis, 10/8/02

By allowing small employers to group together to offer health coverage, Association Health Plans (AHPs) would provide many of the same benefits that exist for large, self-insured companies, says Greg Scandlen of NCPA. These advantages include economies of scale in group purchasing, exemption from state mandates, lower administrative costs, and protection from volatile underwriting cycles.

Making it easier for small businesses to offer health benefits is vitally important since the Census Bureau recently reported only 31 percent of workers at companies with fewer than 25 employees had health insurance in 2001. Small employers are facing 50 to 70 percent premium hikes this year.

In related news, the BlueCross BlueShield Association published a statement in October opposing AHPs, raising concerns of adverse selection and saying AHPs would operate in a regulatory vacuum. Scandlen addresses criticisms of AHPs in Part II of his analysis.

Full text of Part I:
www.ncpa.org/pub/ba/ba419/
Full text of Part II:
www.ncpa.org/pub/ba/ba420/

Medicare Versus Private Insurance: Rhetoric and Reality

Karen Davis, Cathy Schoen, Michelle Coty, and Katie Tenny
Health Affairs, 10/9/02

Karen Davis and colleagues at the Commonwealth Fund report on an extensive survey "that demonstrates that Medicare beneficiaries are generally more satisfied with their health care than are persons under age 65 who are covered by private insurance." They found "sixty-two percent of elderly Medicare beneficiaries reported being very satisfied with their care, compared with 51 percent of those covered by private insurance," and they use the data to argue against a Medicare program offering private, competing health plans.

The study proves what other polls show: Medicare beneficiaries love Medicare, and they use it a lot. But many people with private health insurance are trapped into take-it-or-leave-it plans at work, and many face restrictions on access through managed care that the majority of seniors in Medicare's fee-for-service plan do not. A better measure would have been comparing existing Medicare with the Federal Employees Health Benefits Program, where workers have a choice of competing plans, much like a modernized Medicare would offer. That would provide a better comparison with the kind of plans envisioned for Medicare.

Full text: www.healthaffairs.org/WebExclusives/Davis_Web_Excl_100902.htm

Benefits and Costs of Newer Drugs: An Update

Frank Lichtenberg
National Bureau of Economic Research, 06/02

Frank Lichtenberg, a Columbia University professor and NBER Research Associate, updates earlier research to find many advantages to Medicare beneficiaries of replacing older drugs with newer ones, including reducing hospital costs, fewer doctor visits, and reducing other non-drug expenditures. "A reduction in the age of drugs utilized reduces non-drug expenditure 7.2 times as much as it increases drug expenditure," Lichtenberg writes.

For example, replacing a drug approved 15 years ago with one approved 5.5 years ago would increase prescription drug spending by $18 but reduce other medical spending by $129, yielding a $111 net reduction in total health spending. Using new drug therapies reduces non-drug expenditure by all payers 8.3 times as much as it increases drug expenditure. Lichtenberg also found that the average age of drugs used by Medicare enrollees with private prescription drug coverage is about 8.6 percent lower than the average age of drugs used by Medicare enrollees without either private or public prescription drug coverage.

Full text (pdf): www.phrma.org/publications/publications//2002-10-07.584.pdf

Material for this report is provided by The Galen Institute, P.O. Box 19080, Alexandria, VA 22320, http://www.galen.org. Grace-Marie Turner is president. This report was produced by Elizabeth Lamirand, who can be reached at 703/299-9550, and edited by Conrad F. Meier, managing editor of Health Care News.

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My TURN

BY CONRAD MEIER - MANAGING EDITOR

Real Health Care Reform Means Repealing, Not Passing, Laws

For more information…

WWW The text of ALEC's Mandated Benefits Review Act is available through *PolicyBot*. Point your Web browser to **http://www.heartland.org**, click on the *PolicyBot* icon, and search for document **#6458**.

This year's elections were similar to those in the past in at least one respect: Most candidates for office promised to "do something" to fix the country's imploding health care system. Invariably, their plans involved passing new laws that would create new programs, entitlements, and regulations.

It seems to me these efforts, while well intended, are fundamentally confused. The country's health care system doesn't need more laws: It's already staggering under the burden of having to interpret and comply with thousands of rules and regulations. Instead of passing new laws, we should be *repealing* outdated, counterproductive, and unnecessary old laws.

Flashback

In 1998, I wrote a report for the American Legislative Exchange Council (ALEC) on patient protection laws and mandated health benefits. I reported then that the General Accounting Office (GAO) identified 16 states—Idaho, Iowa, Kentucky, Louisiana, Maine, Minnesota, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oregon, Utah, Vermont, and Washington—as being the most aggressive in passing health benefit mandates and laws regulating insurance providers.

Those 16 states saw their uninsured rate increase 3.5 percent between 1990 and 1994. The 34 less-regulated states saw their uninsured rate *fall* by 2.9 percent. The reasons are obvious. National insurance companies stopped doing business in states with hostile regulatory environments, and local companies and agents dropped the products most affected by the regulations, often individual health insurance.

Consumers in the heavily regulated states also changed their conduct. Employers faced with higher prices dropped coverage for their employees. Individuals delayed purchasing insurance knowing they could buy it after they got sick. People with comprehensive insurance coverage used more medical services, driving up prices and costs.

Community rating, guaranteed issue, and mandated benefits reflect some of the key elements of former President Bill Clinton's failed Health Security Act. These top-down regulations attempt to force the marketplace to respond to what regulators want, rather than what consumers demand and insurers are willing and able to provide. It's a failed approach, not only in health care, but in every industry and in every country it has been tried.

Fast Forward

Four years later, there is a new President in the White House and voters seem more skeptical about government-run health care than they were in the past. But we are still trying to fix what's wrong with health care by passing new laws. A PricewaterhouseCoopers (PwC) study released last May estimated that health insurance premiums would increase 13.7 percent for 2002. PwC attributed 15 percent of the increase to government regulations and mandated benefits.

(Other factors leading to health care inflation include new pharmaceuticals and medical devices (22 percent); rising hospital expenses (18 percent); general inflation (18 percent); and increased consumer demand by a growing senior citizen population (15 percent).)

Regulations' 15 percent of the $67 billion increase in health spending during 2001 is equal to $10 billion, quite a lot of money. Other estimates place the cost of mandates even higher.

"Guaranteed issue, community rating, and government-defined health benefits required the marketplace to respond to regulatory demand, rather than consumer demand."

A study by eHealthInsurance examined 30,000 new individual and family plans purchased by its members in the last six months and discovered the damaging effects of state regulations. The average annual premium for a single policyholder in California, a state without community rating or guaranteed issue, is $1,538. The average premium in highly regulated New York, which imposes both mandates, is more than twice as much at $3,589.

ALEC's Solution

The current pattern of ineffective health care reform could be broken if state legislators embraced the Mandated Benefits Review Act proposed by ALEC in 1998.

The Act creates an independent committee charged with reviewing the cost effectiveness, medical efficacy, and social impact of each health care benefit mandate. All existing mandates would expire within one year of the Act's effective date unless specifically reauthorized by the legislature. All proposed future mandates would require a financial impact study and a positive recommendation from the mandate review committee.

Congress could do the same thing concerning federal mandates by following its own rules, defined in the Congressional Review Act of 1996. Had the sensible men and women of Congress put the mandates in the Health Insurance Portability and Accountability Act (HIPAA) to the test, they may well have concluded the bill was not worth the billion-dollar price tag and attending loss of freedom.

We have tried and tried ... and failed and failed ... to reform health care by passing new laws and creating new programs. It's time to launch a concerted effort to repeal past laws that don't work and let providers, consumers, and insurers work together to get it right.

Conrad F. Meier is managing editor of Health Care News.

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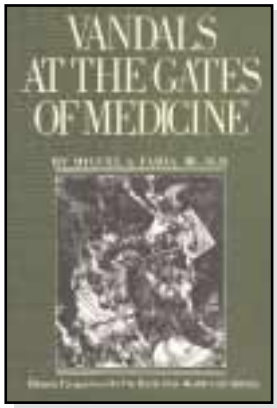


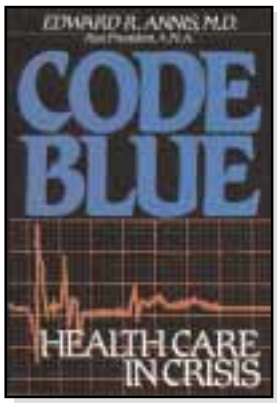
Vandals At The Gates of Medicine

Historic Perspectives on The Battle Over Health Care Reform

Miguel A. Faria, Jr., M.D.

Miguel A. Faria, Jr., M.D. provides compelling arguments that answers to the dilemma of health care reform reside on the pages of history. This fascinating book draws parallels between the past and the present, from a time when the fine line separating myth and history was blurred and indistinguishable to the clearly troubled present.

(403 pp., 1995, Illustrations, Bibliography, Index, ISBN: 0-9641077-0-8, $41.95)



Code Blue

Health Care In Crisis

Edward R. Annis, M.D.

What the press doesn't tell the public—but Dr. Annis does—is that health care problems have a "Made in Washington" label. Code Blue explains how with "minimal changes in our tax laws, Medisave accounts would empower the patient by breaking the tie between job and health insurance and even would allow the gradual phasing out of Medicare."

(278 pp., 1993, Index, ISBN: 0-89526-515-X, $21.95)

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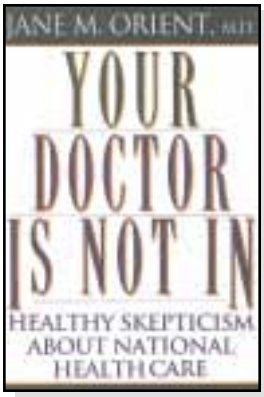
Medical Warrior

Fighting Corporate Socialized Medicine

Miguel A. Faria, Jr., M.D.

In this book of essays, Dr. Faria, argues that managed care and HMOs are not "free market" alternatives, but rather an unholy partnership of government and corporate interests seeking monopolistic government protection to eliminate competition while changing the ethics of medicine from a Hippocratic ethic to a false corporate morality. *Medical Warrior* offers workable solutions to restore medicine to its rightful place.

(207 pp., 1997, Selected Bibliography, Index, ISBN: 0-9641077-2-4, $23.95)

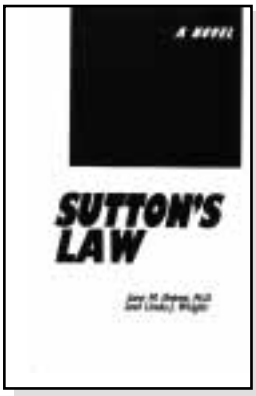


Your Doctor Is Not In

Jane M. Orient, M.D.

In this provocative book, a brilliant, committed physician, a leader in medicine argues for solutions to the crisis in medicine that are bold, thoughtful, and fundamentally opposed to those being widely touted today—including "managed care" systems. From her perspective, there is already too much government involvement in medicine, too much regulation, too much insurance—which is actually prepayment in disguise. These are the root causes of the accelerating rise in fees and costs, the neglect of patients, and stagnation in the science of medicine itself. This book is certain to add fresh energy to the debate over the quality and availability of medical care in America.

(276 pp., 1994, Index, ISBN: 0-517-59011-5, $23.00)



Sutton's Law

Jane M. Orient, M.D. and Linda J. Wright

Sutton's Law is a "frightening realistic novel about where managed care might very well lead us...A mix of medicine, mystery, murder, and intrigue with a little high finance, drugs, and romance—*Sutton's Law* ultimately is about greed and simple justice."

(299 pp., 1997, ISBN: 0-9641077-1-6, $21.95)

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